SUBJECT: Response to Registrant Comments on the Human Health and Environmental Fate and Ecological Effects Preliminary Risk Assessments for Endosulfan

FROM: Stacey Milan, Chemical Review Manager
Special Review and Reregistration Division
Office of Pesticide Programs

TO: OPP Public Docket for Endosulfan

I. Part 1: The Human Health Risk Assessment

The following is the Agency's response to comments (Phase 2) for endosulfan, generated in response to comments submitted by the Endosulfan Task Force (ETF) in Phase 1 of the Proposed Public Participation Process. During Phase 1, the ETF was asked to conduct an "error-only" review of the risk assessment document and submit the corrections to the Agency. Some of the responses serve as clarification or restatement of Agency policies and guidance and it is hoped that this will provide a greater understanding of the Agency's position and procedures on these matters. Comments concerning the rationale behind Agency decisions, endpoints selected, retention of the FQPA factor, and interpretation of available data, are not related to "errors" and will be addressed, as appropriate, following the public comment period (Phase 3).

In the comments (dated 05/10/00), the ETF listed a number of studies/reports that were submitted to the Agency, but were not included in the 02/17/00 risk assessment document. These studies/reports were not submitted in time to be reviewed and evaluated by the Agency. With the exception of the submitted Dietary (Water) Exposure report (MRID # 44953105), which will be reviewed by the Environmental Fate and Effects Division (EFED), the Health Effects Division (HED) has reviewed or is in the process of reviewing and evaluating the data/reports submitted in late 1999 and they will be included, where appropriate, in the revised risk assessment. The ETF has also submitted a residue chemistry report titled, "Frozen Storage Stability of Endosulfan in or on Wheat Grain and Selected Processed Commodities, USA 1998." The Agency has reviewed the report and will incorporate the information into the revised risk assessment as appropriate.

The ETF's recent use-deletion requests were consolidated into a 6(f) Notice issued by the Agency's Registration Division in the July 19, 2000 Federal Register. A 180-day comment period followed the issuance of the 6(f) Notice, during which no comments on the proposed cancellation of uses were received. Following the comment period, these uses were removed from the endosulfan risk assessment. Three prior 6(f) Notices (02/05/97, 02/13/97, and 03/18/98) were issued by the Agency; none of which resulted in any and received no dissenting comments. The crops/uses listed in these Notices were removed from the technical labels of the registrants who are supporting the reregistration of endosulfan and, thus, are also not included in the risk assessment.

II. Endosulfan Product Properties Characterization

ETF Comment 1: According to the submission - Study Record No. A36576 - the water solubility is 0.33 mg/L and the Log P = 4.77.

Agency Response: The available data show that the water solubility of endosulfan varies from "insoluble" to ~0.33 mg/L and the Log P from 4.445 to 5.689.

ETF Comment 2: Endosulfan is not just another organochlorine. CAS classifies it as a "*dioxathiepin*".

Agency Response: Although endosulfan is often referred to as an organochlorine pesticide, the Agency agrees that it can more specifically be classified as a dioxathiepin.

III. Residue Chemistry

ETF Comment 1: The established PAM I methods for endosulfan were used in the submitted residue studies to analyze the endosulfan parents and the sulfate metabolite. Therefore, the ETF believes that no additional recovery data should be required.

Agency Response: The data in FDA Pesticide Analytical Manual Vol. I (10/99 update) Table 302a indicate that endosulfan I, endosulfan II, and endosulfan sulfate are completely recovered by PAM method 302. The Agency will not require additional data for recovery. The data requirements are fulfilled for this guideline study and will be reflected in the next revision of the Revised Residue Chemistry Chapter for the Endosulfan Reregistration Eligibility Decision Document.

ETF Comment 2: ETF has developed the storage stability data on wheat and processed fractions and the report is near completion. The report will be submitted to the Agency in the near future. Oilseed crop storage stability data are not required since the ETF does not support the rapeseed tolerance (reference: use deletion request submitted by task force member companies in July to November 1999).

Agency Response: If stakeholders choose to support the use of endosulfan on rapeseed, safflower, soybeans, and/or sunflower, then storage stability data will be required for an oilseed.

ETF Comment 3: The ETF agrees with the Agency finding that the registration requirements for animal feeding studies are fulfilled. However, The Task Force does not agree with the calculation of the maximum dietary burden for cattle using the pineapple processed residue as 20 to 30% of the diet. Use of this commodity in the cattle diet would be very localized since the only US State where pineapples are grown is Hawaii. Therefore, deriving 96 to

97% of the cattle dietary burden for endosulfan from pineapple processed residue is unreasonable.

Agency Response: As stated in the Revised Chemistry Chapter (01/18/00), the dietary burden calculations are tentative pending field trial data for potential feed items. When all field trial data are submitted and reviewed the dietary burden will be recalculated.

ETF Comment 4: Rape forage - ETF members requested use-deletion in 1999 for the rapeseed crop (including canola); peas (dried/seed crop only)- the FIFRA 6(f)(1) use deletion was published in 62 FR 6776-6777, dated 2/13/97 and 63 FR 13246-13248, dated 3/18/98. Sugarcane-ETF does not support the US tolerance for this crop.

Agency Response: If stakeholders other than the task force wish to support the use of endosulfan on rapeseed or peas (dried/seed crop only) or sugarcane, additional data will be required.

ETF Comment 5: With this response, the Task Force is making a new request to the Agency for the translation of carrot and potato residue data to support turnip root. The existing acceptable residue studies for carrot and potato roots showed residue levels to be 0.05 ppm. We will propose similar tolerance for the turnip root based on these root crop data. A justification was provided.

Agency Response: Residue data for carrot and potato will be examined for the appropriateness of translation to turnip for the next revision of the chemistry chapter.

ETF Comment 6: Recent field trial data exist for cotton gin-byproducts from cotton treated with endosulfan after bolls open. These studies (MRID Nos. 44854101 and 44854102) had been reviewed and found to be acceptable to support a new tolerance of 28 ppm for the combined residues of endosulfan. The approval statements by the reviewer are as follows (DP barcode No.: D258716, memo by Sherrie Mason dated December 10, 1999) ...The Agency stated that "no cotton gin-byproducts data reflecting treatments made to cotton plants until bolls open have been submitted; however, because residues are expected to be lower from this use pattern, RRB2 will not require additional cotton gin byproducts data for reregistration. The registrant must submit a Section F proposing a tolerance for cotton gin byproducts. RRB2 recommends a tolerance of 28 ppm..."

Agency Response: No additional residue data for cotton treated with endosulfan before bolls open will be required. This statement will be added to the next revision of the chemistry chapter.

ETF Comment 7: We are requesting that the Agency review the study (GLN 860.1500 Crop Field Trials) and inform us of the results as soon as possible.

Agency Response: The study has been reviewed and is in QA/QC process. The review results will be transmitted to the ETF as soon as they are available and included in the next chemistry chapter update.

ETF Comment 8: As stated by the Agency, confirmatory data for tobacco residues is a new requirement for use of pesticidal chemicals on tobacco. Based on our preliminary review, some tobacco residue data conducted with endosulfan are available within the task force companies and a few appeared to have been on file with the Agency. ETF needs clarification regarding this issue, and which data are still being required.

Agency Response: Residue chemistry data requirements are detailed in an Agency memorandum dated 7/14/1995 from M. Metzger and E. Zager to HED Chemistry Branches' personnel. The Agency has provided this memo to the task force.

ETF Comment 9: We believe there is an entry error for the "watercress." Instead, the crop referred to appears to be for "rapeseed," basing on the statements that follow which refers to 'canola oil.' More importantly, as noted in the Task Force letters submitted in July to November of 1999, the Task Force is supporting the existing tolerances for raspberries (0.1 ppm) and mustard seeds (0.2 ppm), although these crops are currently not listed on the main product labels. We are not aware of any additional residue data requirement for keeping these existing tolerances. Also, there exist interests through IR-4 involvement to establish a caneberries subgroup tolerance of 0.1 ppm (raspberry and blackberry, IR-4 data). For sugarcane, the Task Force is not supporting the US tolerance for sugarcane, as noted in the top section above.

Agency Response: Watercress is the correct reference. A correction to include raspberries and mustard seed for crops the task force is willing to support will be made to the next version of the chemistry chapter.

Status of a Submitted Study

ETF Comment 11: The Task Force wishes to bring to the Agency attention the status of one submitted residue chemistry study (MRID No.: 44762901). The study is titled as "Magnitude of Endosulfan Residues in or on Wheat Grain and Processed Commodities Resulting from Two Applications of Phaser Insecticide in an Exaggerated Rate, USA, 1998", by S. Scott Brady, Residue Chemistry Department, AgrEvo/Aventis CropScience USA. February 1999 (Aventis Record No.: C000915).
We submitted the study in early 1999 and based on our record, the report had been reviewed and found acceptable by HED pending the submission of the required storage stability data (memo by Stephen DeVito dated 5/27/99; DP Barcode No D253976). However and for reasons unclear to us, the Agency made no mention of this study in the Agency references or of its contents in the HED Chapters.

Agency Response: The study will be included in the next revision of the chemistry chapter.

IV. Endosulfan Dietary (Food) Assessment

ETF Comment 1: The 1994-96 CSFII consumption database is now available for use in the DEEM™ program. This database would be more reflective of the latest eating habits of the US consumers. Additionally, the follow up efforts on the outliers and errors in the CSFII database has tended to be more rigorous in recent years and should lead to more reliable estimates of exposure for the populations.

Agency Response: Currently, EPA is using the 1989-1992 CSFII consumption data; however, in the near future, EPA will be incorporating the 1994-1996 and 1998 CSFII consumption data and the recipes/translation data into the dietary exposure assessments.

ETF Comment 2: The ETF believes and has provided appropriate comments within ETF's toxicology Chapter Response that a threefold FQPA safety factor should not be retained based on the Agency's evaluation: "*based on the animal studies conducted under OPPTS guidelines there is no evidence of increased sensitivity or susceptibility of the fetus, infants or children to the toxicity of Endosulfan*" (HED chapter, p.3).

Agency Response: See Toxicology responses.

ETF Comment 3: The ETF member companies have submitted many processing studies to EPA for the various endosulfan commodities during the Endosulfan Reregistration Process. These studies have been reviewed and accepted by EPA. The factors and data generated by these processing studies should be incorporated in the endosulfan risk assessments. These include the new processing studies for grapes, potatoes, tomatoes, and wheat plus the existing studies on file at the Agency for apples/pome fruits and other stone fruits. References to most of these data were cited in the current HED Residue Chapter dated February 2, 2000. The wheat processing data was not mentioned, but our records show that it had been reviewed by HED July 1999 (memo by Steve Devito, DP Barcode D253976).

Agency Response: The Agency agrees that the data from the reviewed processing studies should be incorporated into the dietary assessment when appropriate; therefore, the suitable processing data will be incorporated into future dietary assessments of endosulfan.

ETF Comment 4: We commend the Agency for applying this recently developed method to the risk assessment. However, it is not clear from the draft chapters which method EPA used for decompositing. Recently three methods were discussed at the March 1, 2000 SAP "Comparison of Allender, RDFgen and MaxLIP Decomposition Procedures." It was clear at this SAP that the different methods affect the outcome of the distribution and possibly the risk assessment and also that EPA does not at this time endorse one method over the others. Thus a reference to which decompositing method that EPA had incorporated would be helpful.

Agency Response: In the Agency's dietary exposure assessments of endosulfan, the monitoring data for apples, carrots, oranges, cucumbers, lettuce, melons,

peaches, pears, peppers, potatoes, squash, and tomatoes were decomposited using the H. Allender method.

ETF Comment 5: EPA included several crops in their risk assessment, which the ETF does not support and which have been deleted from the current ETF labels. Therefore these crops should not be included in the RED risk assessments. These deleted crops are (FR Notice Vol. 62, p. 5398-5399, February 5, 1997): alfalfa (grown for forage), artichokes, field corn, peas (dried/seed crop only), safflower, sugar beets, sunflower, and watercress. Alfalfa was included as a component of the ruminant dietary burden calculations and thus this calculation is incorrect.

Agency Response: Dried peas were not included in the Agency's dietary assessment; however, a tolerance exists for succulent peas which were incorporated. Field corn, citrus fruits, endive, garden beets, and rapeseed will be removed from the revised dietary exposure assessments of endosulfan. As for the remainder of the crops listed (alfalfa, artichokes, safflower, sugar beets, sunflower, and watercress), they will not be included and, the ruminant dietary burden will be recalculated in the revised dietary exposure assessments of endosulfan.

V. Toxicology

ETF Comment 1: The ETF does not support the Agency's selection of the 21-day dermal toxicity study in the rat (Acc No.: 257684/257685) in establishing the NOAEL for use in short- and intermediate/long-term exposure. The NOAEL for this study was established at 3 mg/kg/day with a LOAEL of 9 mg/kg/day. ETF cites four other dermal toxicity studies that support a NOAEL of 9 mg/kg/day.

Agency Response: The Agency reevaluated the toxicology endpoints for use in short and intermediate/long-term exposure on January 11, 2000 (HED Doc No 014024, dated January 31, 2000). The Hazard Identification Assessment Review Committee (HIARC) re-affirmed the selection of the dermal toxicity study (Acc No.: 257684/257685) with technical endosulfan (97.2% a.i. w/w), basing their conclusions on effects observed at 9 mg/kg/day (LOAEL). These findings include mortality with clinical signs in males and increased liver abnormalities (enlargement of parenchymal cells, loss of cytoplasmic basophilia, isolated cell necrosis, and frequent mitosis). The toxicology endpoints are supported by another 21-day dermal toxicity study (MRID 41048505) in which clinical signs (tremors, straub-tail, spasms) and mortality occurred in females treated dermally with 12 mg/kg/day of a 33.3% formulation of endosulfan.

ETF Comment 2: The ETF does not agree with the Agency's requirement that a developmental neurotoxicity study with endosulfan be performed and that an FQPA safety factor of 3x should be retained due to the uncertainty associated with this data gap.

Agency Response: The Agency reviewed the toxicology database for indications of increased susceptibility of rats and rabbits to *in utero* and/or postnatal exposure to

endosulfan. Although developmental toxicity was only seen at or above parentally toxic doses, there were treatment-related clinical signs of neurotoxicity following oral exposures in the rat, rabbit and dog, and via the dermal route in rats. To fully assess the neurotoxic potential of endosulfan, acute (OPPTS 870.6200, OPP 81-8) and subchronic (OPPTS 870.6200, OPP 82-5) neurotoxicity studies in the rat were requested by the Agency. The acute neurotoxicity study was reviewed and found to be acceptable/guideline. The subchronic neurotoxicity study has not been received by the Agency and remains a data gap. Based on this data gap, the (HIARC) recommended that the requirement for a developmental neurotoxicity study be placed on reserve pending receipt and favorable review of the subchronic neurotoxicity study. Subsequently, the FQPA Safety Committee reviewed the hazard and exposure data for endosulfan on November 2, 1998 and recommended that the FQPA Safety Factor be reduced to 3X. Further, the committee concluded that a developmental neurotoxicity study in rats is required for endosulfan because of the Committee's concern for 1) fetal effects reported in the open literature (Lakshmana and Raju, Toxicology; 91: 2, 1994: 139-150); 2) the severity of effects seen in female offspring of the F0 generation (increased pituitary and F1b generation (increased uterine weights) at the high-dose when compared to the toxicity observed in parental animals at this dose in the two-generation reproduction study in rats; and 3) the subchronic neurotoxicity study will only address the neuropathological concerns resulting from exposure to endosulfan. A developmental neurotoxicity study will provide the critical data needed to demonstrate the toxic effects of endosulfan on the developing fetal nervous system.

ETF Comment 3: The ETF contends that endosulfan is not an endocrine disruptor.

Agency Response: The concern that endosulfan may be an endocrine disruptor is based on reports in the open literature and in studies submitted to the Agency. The Agency's weight-of-evidence that endosulfan may be an endocrine disruptor is presented in Appendix A of the HED Toxicology Chapter (HED DOC Number: 014049, dated November 12, 1999). The ETF has submitted its own weight-of-evidence report (MRID 44939102) in evaluating the potential endocrine effects of endosulfan; this study has not yet been reviewed by the Agency. Pending review of this report and evidence to the contrary, the effects observed in open literature and studies submitted to the Agency are suggestive of endocrine-related effects due to endosulfan.

VI. Occupational and Residential Exposure

ETF Comment 1: The use patterns of endosulfan do not produce long-term occupational exposure and the Agency's assessment correctly does not calculate any long-term occupational exposure. Table 2 of the occupational assessment document should delete the columns pertaining to long-term dermal and inhalation exposure assessment, as these assessments are not relevant to the endosulfan exposure assessment.

Agency Response: Long term occupational exposure to endosulfan was not assessed in the revised human health risk assessment since the only scenario with a long term exposure duration, the use of endosulfan in a smoke cannister, was deleted from the endosulfan technical as a result of a 6(f) notice issued at the request of the ETF.

ETF Comment 2: Reference 7 of the Agency occupational exposure risk assessment cites the May 1997 version of the PHED (Pesticide Handler Exposure Database) surrogate exposure guide used by the Agency in lieu of actual PHED product relevant subsets. A more recent August 1998 version of the surrogate guide exists and should have been used. Because the differences between the two versions are minimal and did not affect the endosulfan evaluation, the more recent version may well have been used. The citation should be updated if applicable.

Agency Response: The citation will be updated in the revised occupational/residential chapter during Phase 4 of the Proposed Public Participation Process. There were some differences between the August 1998 version of PHED and the unit exposure values stated in the occupational/residential chapter. The unit exposure values will be changed to reflect the August 1998 PHED version in the revised human health assessment that will be produced after the Phase 3 public comment period.

ETF Comment 3: All labels supported by the ETF are consistent with the Worker Protection Standard requirements for personal protective clothing (PPE).
The PPE requirements for EC-formulations include coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, and the use of chemical-resistant headgear during overhead spraying and chemical-resistant apron when cleaning, mixing and loading. The PHED estimates of unit exposure for the PPE scenarios reflect the use of the protective gloves and the double layer of clothing. However, the PPE scenario unit exposure estimates for air blast applications and flagging do not reflect the requirement for the use of chemical-resistant headgear during these overhead applications. An exposure mitigation factor should be applied to the head and neck exposure component of the air blast applicator and flagger dermal exposure estimates to account for the exposure reduction obtained by the label required protective headgear.

The ETF realizes that the PHED surrogate exposure guide does not propose an exposure mitigation value for headgear as it does for double-layers of clothing, protective gloves, or respiratory protection. The ETF is unaware of the reason for this omission. Based on a 50% reduction in dermal exposure to the head and neck by the use of the protective headgear, the total dermal exposure to an air blast applicator using open-cab equipment is reduced from 0.22 mg/lb a.i. to 0.12 mg/lb a.i. Likewise, the flagger dermal exposure is reduced from 0.01 mg/lb a. I. to 0.007 mg/lb a.i. to reflect the 50% reduction in head/neck exposure afforded by the required headgear protective equipment. The ETF requests that the Agency either incorporates the exposure reduction afforded by the required headgear or provides a clear rationale of policy as why such

headgear protection is not incorporated into the exposure assessment.

Agency Response: The Agency agrees that chemical resistant headgear may reduce pesticide exposure. A protection factor has not been established by the Agency for the use of headgear; therefore, occupational exposure risk estimates are not quantitatively reduced to take this protective clothing into account. One problem in setting a generic protection factor for chemical resistant headgear is that headgear can come in a wide range of styles, materials, etc. For this reason, the amount of protection that headgear provides varies widely. Even so, the MOEs for airblast applicators presently range from 3.2 to 8 at the additional PPE mitigation level for dermal risk. The use of a 50% protection factor for head/neck exposure would not increase the highest MOE to more than 12, which is still far below the target MOE of 100. The Agency will take into consideration any data submitted to support ETF's assumption that chemical resistant headgear reduces head/neck exposure by 50%.

ETF Comment 4: The Agency has estimated the exposure to an applicator in an enclosed cab during airblast application by using the PHED surrogate guide estimate of 0.019 mg/lb a.i. for the single layer of clothing and protective glove scenario, but increasing the hand exposure estimate of 0.0129 mg/lb a.i. with protective gloves, 10-fold to estimate the exposure without gloves. This extrapolation is necessary because PHED does not contain any exposure data for airblast applicators in enclosed cabs in which protective gloves are not worn. The no-glove scenario is necessary because an applicator using engineering controls such as an enclosed cab is not required to use protective gloves.

Because of the absence of no glove hand data, the Agency back-calculated from the gloved hand exposure of 0.0129 mg/lb a.i. to no-glove hand exposure by using the 90% glove protection default. This increased the hand exposure to 0. 129 mg/lb a.i. and the total dermal exposure to 0. 14 mg/lb a.i. Despite the significant decrease in total dermal exposure that is produced by the use of enclosed cabs, the engineering control estimate is almost the same as the open cab airblast exposure estimate of 0.22 mg/lb a.i.

The error in the back-calculation results from the use of the 90% protection default that is appropriate in scenarios where no engineering controls exist to a scenario involving engineering controls. Because the enclosed cab is so efficient in reducing dermal exposure (0. 197 mg/lb a. I. to 0.00418 mg/lb a.i. or 98% for the head and 0.0421 mg/lb a.i. to 0.00186 mg/lb a.i. or 96% for the torso and limbs) the addition of protective gloves in an enclosed cab will not reduce the unprotected hand exposure an additional 90%. The total deposition of dermal exposure outside the clothing to the arms, legs, and torso of an airblast applicator was 1.86 mg/lb a.i. in an open cab and 0.045 mg/lb a.i. in an enclosed cab. The enclosed cab reduced dermal deposition 98%. Therefore a comparison of open cab to enclosed cab deposition indicates a 95% to 98% reduction in exposure and an additional 90% reduction in hand exposure from gloves is unlikely.

The 90% default for hand exposure reduction by protective gloves of the applicators is not realistic. This can be ascertained by comparing the hand dermal exposure estimates for groundboom applicators. The hand exposure to open-cab groundboom applicators was 0.0065 mg/lb a.i. without gloves and 0.00629 mg/lb a.i. with gloves. There is essentially no difference, and hand exposure without gloves was not 10-fold higher than with gloves for the applicator. Similarly, hand exposure for groundboom applicators in enclosed cabs are nearly identical with gloves at 0.0009 mg/lb a.i. and 0.000836 mg/lb a.i. without gloves. The exception to this rule involves open cab airblast applicators where the protective gloves were efficient in reducing the heavy mist deposition. Unprotected hand exposure was 0.123 mg/lb a.i. compared to 0.00243 mg/lb a.i. when gloves were a barrier to the deposition of the airblast mist. Such deposition does not occur in the enclosed cab.

Because the use of the 90% default back-calculation is inappropriate for a combined enclosed cab and protective glove scenario, the ETF proposes that the PHED data be used to select a more appropriate default for the enclosed cab airblast applicator hand exposure. Based on the 95% to 98% reduction in dermal exposure to the head and torso/limbs a 95% reduction in the bare hand open-cab dermal exposure estimate of 0.123 mg/lb a. I. is an appropriate default to estimate bare hand exposure for applicators in an enclosed airblast sprayer. The estimated hand exposure is 0.0062 mg/lb a.i. and the total dermal exposure to an airblast applicator in an enclosed cab is 0.012 mg/lb a.i. The occupational exposure assessment should correct these errors in their assessment for hand exposure.

Agency Response: The Agency will assess the airblast applicator at the engineering control mitigation level using the 0.019 mg/lb ai unit exposure since these are the actual study data. This change will be incorporated into the revised HED assessment. The registrant is always encouraged to submit applicator exposure studies on endosulfan.

ETF Comment 5: The Agency estimated the MOEs for mixer/loaders and applicators based on the type of mixing/loading operation and the application equipment used along with the standard HED default acreage and several application rates (worst case, not always represented by the ETF labels) within each exposure scenario. The ETF knows that this is the standard approach employed by HED for operator exposure and risk assessment. However, this approach is incorrect and inconsistent with the requirements of FIFRA that require a risk/benefit based regulatory decision-making process. As the risks and benefits of endosulfan vary for each individual crop and application scenario, the Agency's approach to estimating occupational exposure and risk must also be crop-specific, in accordance with the current ETF end-use product labels. The exposure scenario approach as used by HED in the occupational risk assessment is only useful as a screening approach for identifying potential risks based on extremely conservative default assumptions. Therefore the ETF considers the assessment as incorrect. The key crop specific information, necessary to conduct an accurate, specific exposure assessment was submitted by ETF to the Agency on 28 September 1999. This document appears to have

been evaluated by HED based on comments in the third bullet of the "Data Quality and Confidence in Assessment" section (page 50 of the occupational risk assessment). But it appears that this information, based on actual use data, was not utilized by the Agency. It seems that HED did not understand how the ETF estimates were arrived at and that HED believes that the magnitude of the differences were not sufficient to significantly impact the assessment.

The ETF would like to provide HED with any assistance to ensure that the most appropriate data set is used. ETF would like to discuss with HED the submitted exposure estimates in more detail. The sources of information used by the ETF are all readily available to the Agency for confirmation. These sources were the U.S. Census Bureau of Agriculture, the Agency's own Quantitative Use Assessment, the 1996 Doane Marketing Survey, and the Pesticide Handlers Exposure Database surrogate guidance document estimates of exposure. The daily exposure algorithm was essentially the same one used by EPA to estimate exposure and the equations are provided in the ETF submission. Therefore we are concerned to see why the Agency has problems to understand how the submitted estimates were arrived at. Because the ETF submission remains germane to the endosulfan occupational risk assessment, a detailed review with specific, rather than broad stroke comments are necessary.

The second comment by the Agency that the magnitude of the difference between the ETF estimates and the Agency estimates is incorrect for certain crops. One would expect, and one finds, minimal differences when the average acreage for a specific crop is similar to the Agency acreage default value. However, for crops such as apples, watermelons, tomatoes, and tobacco there is a significant difference between the groundboom and airblast default acreage and the average acreage for these crops as reported in the Census of Agriculture, as well as the actual application rates. It is important to address the exposure and risk on a crop basis because different risk mitigation options become more obvious than using the Agency exposure scenarios. For example, a PPE MOE of 80 at a 3.0 lb a.i./A application may broadly indicate that engineering controls are required using the current Agency exposure scenario set-up. However on a crop specific basis this same estimate of 80 may permit the determination that reducing the maximum application rate for that crop to 2.25 lb a.i./A would still maintain efficacy and permit continued use of the label-required PPE. The risk-benefits analysis required by FIFRA may indicate that endosulfan use on this crop has high benefits and that the MOE of 80 is acceptable based on high benefits. A correct assessment of occupational exposure requires a crop-specific based assessment to permit the FIFRA mandated risk/benefits analysis.

Agency Response: The submission titled “Assessment of Human Exposure from the application of Endosulfan,” by Kelly White. Jellinek, Schwartz & Connolly Inc., September 28, 1999. (MRID 44939101)- Submitted on October 4, 1999 is under review by the Agency. The issue of acres treated per day is not considered an error and will be addressed in the revised risk assessment.

ETF Comments 6: The ETF submitted endosulfan-specific dislodgeable foliar residue (DFR) studies to the Agency (MRID# 44403102) for use in the calculation of restricted entry intervals (REIs).

The studies were conducted in three representative crop groupings, melons for low crops, peaches for tree crops, and grapes for high trellised crops in accordance with Guideline 875.2000 guidance. In addition, the ETF also quantified the DFRs within each crop grouping for the emulsifiable concentrate (EC and wettable powder (WP) formulations. The guidance document provides discussion that different formulations may produce different DFR dissipation profiles for similar uses on the same crops. Indeed, the endosulfan studies demonstrated that the dissipation curves for the liquid and wettable powder formulations were different. The HED occupational exposure assessment acknowledges the difference in the DFR values between the EC- and WP formulations. The Agency erred in selecting only the WP DFR data to calculate the REls for endosulfan because it represents the worst-case. Because the two formulations have different dissipation curves the formulation-specific dissipation curves must be used to set the formulation-specific REIs. Therefore, the WP DFR data are appropriate for WP- labels only and the EC DFR data are to be used to set REIs specific for EC- labels as is consistent with the intent of the 875.2000 guidelines.

The transfer coefficients (TCs) used by the Agency in the endosulfan postapplication exposure assessment are default values consistent with Policy Memo Number 3. As stated in the background of the memo, the default values are a reference when no agricultural postapplication exposure data are available. The Endosulfan ETF members are also members of the Agricultural Reentry Task Force (ARTF) and as such may cite and utilize data submitted to the Agency by the ARTF. The ETF is therefore emphasizing to the Agency that data submitted by ARTF must be used and that the Policy 3 default values are to be used only in the absence of data.

The ETF is concerned about an internal and deliberative HED memorandum of 25 February 1999 from Jack Arthur. That memorandum appears to imply that if data from one study are substantially different from the default TCs, the data from the study should not be used as a surrogate in lieu of the default TC. Specific to the citrus situation addressed by the memorandum, the memorandum concluded that *it would not be appropriate to use the results from the one study resulting in a TC of 2000, for all other pesticide/citrus harvesting scenarios -that is what our default values were specifically designed to do.*

The ETF understands the Agency's concern that the results from any study may differ from either their default TC or the results of other studies (either completed or planned). The Agency's collective experience understands that the TC value for any given crop/activity will be variable when comparing the results of individual studies. Ideally the TC will be obtained from the results of several similar studies, which will supersede the results of one individual study.

However, the results of one or more studies are to be used in place of a default coefficient, even if the result does not agree with the predetermined default.

The following table contains a tabulation of worker reentry studies submitted by ARTF to the Agency. The data from these studies are to be used in lieu of the default TCs as is consistent with Policy.
The submitted ARTF studies that contain DFR and worker reentry exposure data that permit the calculation of transfer coefficients can be broadly classified into the following categories: Scouting and Weeding, Low crop harvesting, Medium crop harvesting, High crop harvesting, Grapes harvesting/turning, and Tree harvesting.

There are nine studies that looked at reentry exposure during weeding and scouting in sweet corn, cauliflower, dry peas, sunflowers, grapes, cotton, and beans. The ARTF estimated TCs ranged from 36 cm^2/hr to 1,180 cm^2/hr. The geometric mean TC is 153 cm^2/hr, which reflects the preponderance of TCs at the lower end of the range.

Two strawberry harvesting studies and a tomato harvesting study had TCs of 874 cm^2/hr and 1,266 cm^2/hr, and 611 cm^2/hr, respectively. The geometric mean of 878 cm^2 /hr should be used in place of the low potential hand harvest default of 2,500 cm^2/hr. Likewise, the medium height harvesting TCs from two studies (4,290 for cauliflower and 725 for tobacco) 1,764 cm^2/hr should be used in place of the medium potential hand harvesting TC of 4,000 cm^2/hr.

ARTF has submitted three studies in which TCs are available for grape harvesting and other high contact grape activities. The TCs were 3,927 cm^2/hr, 6,840 cm^2/hr, and 2,928 cm^2/hr with a geometric mean TC of 4,284 cm^2/hr. This data base TC should replace the default 15,000 cm^2/hr used in the absence of data. The geometric TC for harvesting tree crops was 2,011 cm^2/hr obtained from four studies and should replace the default TC of 10,000 cm^2/hr.

The ETF understands that additional DFR and TC data will be submitted by the ARTF, however the magnitude of refinement in the TCs will be limited compared to the significant refinement obtained in going from the default values to the data derived TCs calculated by ARTF. Therefore, any reticence on the part of HED to use submitted reentry data are outweighed by the regulatory obligation to utilize all submitted data that meet guideline requirements. The impact of using the ARTF based TCs in lieu of the default TCs and using the endosulfan EC- DFR data rather than the WP- formulation data, which are appropriate only for the wettable powder formulation, is significant on the estimation of the correct REIs.

An example of the impact is illustrated with harvesting tomatoes. Table 14 of the HED assessment for occupational exposure estimated a 32-day REI for tomatoes based on a 3 lb a.i./A application rate, a wettable powder based DFR of 0.024 ug/cm^2, and a TC of 10,000 cm^2/hr based on tomatoes

being considered a high potential exposure crop. In reality, the ARTF scoping effort would place tomatoes in the low crop cluster with a harvesting TC of 878 cm^2/hr. The ARTF tomato harvesting study submitted to the Agency had a TC of 611 cm^2/hr. The label maximum application rate for tomatoes is 1.0 lb a.i/A and not the generic 3.0 lb a.i./A used by HED. Therefore the 3-fold increase in the melon DFR values to adjust from the study application rate of 1.0 lb a.i./A to the generic 3.0 lb ai/A rate is inappropriate. This further illustrates why the endosulfan REIs must be calculated on a crop specific basis and not on crude clusters that do not account for the different application rates.

Using the ARTF data derived TC of 878 cm^2/hr, an 8-hour workday, 70-kg body weight, and the dermal NOEL of 3 mg/kg/day (EPA's used endpoint), the DFR value that provides a 100 fold MOE is 0.3 ug/cm^2. Based on the endosulfan DFR data, dislodgeable residues of 0.3 ug/cm^2 or less are reached on Day 2 for the EC and Day 5 for the WP. Therefore the Agency should propose REIs of 48 hours for the EC and 5 days for the WP on tomatoes, rather than the 32 days calculated in the occupational assessment. Based on the NOEL of 9 mg/kg/d the calculated REI would be less than 24 hours for the EC and less than 48 hours for the WP.

The ETF concludes that the correct estimation of the REIs in the HED risk assessment must account for the different dissipation curves of the two distinguished formulations as provided by the submitted DFR data. It must also account for the crop-specific application rates, the appropriate toxicological endpoint, and must utilize the TC values from studies submitted by the ARTF rather than default values intended for use in the absence of data. The ETF is planning to submit a refined assessment for occupational postapplication exposure, using the available use data (similar to the one submitted with the mixer/loader/applicator assessment), resulting in crop and activity-specific REI calculations.

Agency Response: The Agency used standard values for the transfer coefficients from the Exposure Science Advisory Council Policy, which is based on published literature studies, submitted guideline studies and best professional judgement. Data from the ARTF are still being submitted and reviewed by the Agency. The ARTF data will be used in future assessments when the data has been evaluated. The comments on the use of wettable powder versus emulsifiable concentrate data and the use of the 2000 transfer coefficient for citrus crops are not considered error only comments and will be addressed in the revised risk assessment.

ETF Comment 7: We have noted that the current HED chapters for endosulfan have not included the contents or Agency reviews for several keys reports submitted by the Task Force during October to November 1999. We request that the Agency will review these relevant studies as soon as possible so that the information can be incorporated into the next revised HED Chapters for public comments.

The studies include the following: Application worker exposure (MRID 44939101)- Submitted on October 4, 1999, titled "Assessment of Human Exposure from the application of Endosulfan" By Kelly White Jellinek, Schwartz & Connolly Inc. September 28, 1999.

Agency Response: This submission will be reviewed by the Agency, but will not be incorporated into the current risk assessment for public comments since the issues raised in the submission are not considered error only issues.

ll. Part 2: The Environmental Fate and Ecological Effects Risk Assessment

The Agency's Environmental Fate and Ecological Effects Division (EFED) has reviewed its ecological assessment for scientific and technical errors noted in the Endosulfan Task Force (ETF) response. In addition, broader statements made by the ETF were evaluated to determine the scientific merit of those comments and to determine whether any interpretative comments warranted changes in the risk assessment. In response to the ETF comments, scientific/technical corrections and revisions to the assessment were made as necessary. Additionally, the risk characterization was clarified and revised as warranted by the comments. Below the Agency responds to the registrant's comments.

(1) Conservatism of the Assessment

ETF Comment: The ETF believes the assessment is not "non-conservative*"* based on current day usage and that the assumptions made for aquatic assessment and the use of the maximum label rates (instead of e.g. "typical" rates) for calculating acute risk quotients [terrestrial exposure] is not a "non-conservative" approach. The ETF believes the risk quotient calculations should be modified to reflect realistic conditions. The wording "non-conservative" is not correct and should be deleted from the risk assessment. Further, the aquatic risk assessment does not represent a "non-conservative" or "typical" scenario.

Agency Response: The assessment has been revised to more clearly note that the aquatic assessment was refined but the terrestrial assessment is a screening level assessment. Specific issues pertaining to the conservativeness of the assessment are addressed below. However, the Agency believes that the assessment is nonconservative, particularly with respect to use of typical application rates and exclusion of the toxic contributions of endosulfan sulfate in the risk assessment.

The refined risk assessment for aquatic impacts reflects typical use rates, not maximum label rates, and assumes only one application per year. Thus, it is not conservative in those areas where endosulfan is used at maximum allowable label applications and/or where it is applied more than one time in a year.

In addition, because the Agency did not consider the contributions of endosulfan sulfate in its exposure assessment, the assessment underestimates the impacts of the combined toxic residues. Although the terrestrial risk assessment is not refined to the same degree as the aquatic assessment, it did not consider the contributions of endosulfan sulfate in the terrestrial exposure.

(2) Interpretation of Incident Data

ETF Comment: The ETF believes that incident data confirming current endosulfan use represents a serious risk is misleading and that all the incidents irrespective of the causes (Registered Use, or Misuse, or N/R) were analyzed together. According to the ETF, EPA's

conclusions from the incident data were drawn towards the registered use of endosulfan. The available incident database, especially for California, indicates that the number of incidents from registered endosulfan uses has significantly decreased. In addition, the statement regarding the high percentage of nontarget mortality resulting from endosulfan in the EIIS is incorrect and should be deleted. The statement would be only true if values are included before the application rate reduction and label changes including mitigation measures (see 300 ft. buffer) were in place.
Further, incidents mainly occurred before the rate reduction and label changes including mitigation measures were in place; especially if one considers the 33% (29) of the total incidents in California occurred since 1971. Out of the 29 reported cases 20 were recorded in the '70s, 5 in the '80s and 4 in 1996. Only one of the four reported incidents in 1996 was caused by the registered use of endosulfan, the other three were either misuse or the cause could not be identified. This trend clearly shows that the California mitigation measures as enforced by permit restrictions in the late 80s, and consequently incorporated on the ETF product labels (officially approved in April 1992) are effective and demonstrate that the use of Endosulfan under those conditions is safe.

After the change in application rates and incorporated label mitigation measures (especially in California), the incident database does not confirm EPA's statement. Finally, the presentation of the incident data is somewhat misleading because in several plots of incident data for different States presented by EPA, the years without incidents are missing. This gives the impression that there were endosulfan-related incidents happening every year.

Agency Response: The analysis of the Environmental Incident Information System was not specific to endosulfan use patterns. As reported in Appendix G of the assessment, only 34% of the reported incidents were attributable to misuse (intentional and accidental); 29% were a result of the registered use of the compound, and 37% resulted from some unspecified use. In the 1970's and the 1980's a total of 42 and 22 endosulfan-related incidents were reported, respectively; although incidents for the 1990's are still being tallied, a total of 37 incidents have been recorded and roughly 72% of these were either due to registered use or their cause was not reported. Peaks in the number of incident reports occurred as recently as 1996, and only 20% were associated with misuse of the pesticide. The fact that incidents continue to be reported even though the ETF has voluntarily imposed application restrictions indicates that impacts to non-target animals are possible even when a 300-ft buffer requirement is on the product labels.

ETF Comment: The ETF disagrees with the Agency regarding the inclusion of non-US incidents in the risk assessment. The ETF feels this reference should be deleted because the use patterns, and backgrounds for these incidents may not relate to the conditions in the US, both from a practical use and awareness standpoint. Additionally, as with all incidents, the reporting of such in a paper does not necessarily mean that the effects reported were actually caused by endosulfan, but only that the author may have made a connection. The relevance of findings outside US is questionable as use conditions, methods and awareness of environmental contamination differ greatly. An anecdotal reporting creates the impression of evidence, while the selection of the monitoring data is arbitrary.
Agency Response: The Agency acknowledges that incidents outside the US need to be considered in relation to possible differences in use and environmental conditions. The risk assessment conclusions are based on incidents reported within the US and not from other countries. The Agency has moved this section out of the body of the assessment and into the supporting literature appendix.

ETF Comment: This statement [the EIIS is useful for documenting ecological field effects that

substantiate EFED concerns about nontarget mortality] is disputable; the sentence should be deleted. That statement would only be correct if the incidents cited indeed would have been caused by endosulfan under normal use conditions. As even EPA states that the EIIS may not reflect an unbiased estimate, the reference is only a weak proof.

Agency Response: The Agency has emphasized the biases associated with the EIIS; however the data base serves as a useful index to gauge the effects of pesticides on nontarget organisms. As indicated previously, minimally 29% of the reported incidents resulted from the "registered use" of the pesticide. While the full details surrounding the incident are not captured in the risk assessment, it is reasonable to assume that normal use conditions could be equated with "registered use."

ETF Comment: Most of the reported fish kills occurred before rate reductions and label changes including mitigation measures were in place. Thus the reference [to NOAA's assessment that endosulfan was responsible for more fish kills in U.S. estuaries and coastal rivers between 1980 and 1989 than all currently used pesticides at that time] should be deleted.

Agency Response: Although rate reductions were not in place at the time, the conclusion of NOAA remains valid. These incidents did occur and they provide an indication as to the magnitude of impact endosulfan has had on nontarget aquatic organisms.

ETF Comment: The reference [to fish deaths in estuaries and coastal waters in the 1980's] should be deleted. The statement is a contradiction in itself by stating that endosulfan was responsible for fish kills, while its analytical quantification is difficult.

Agency Response: While the Agency is not always able to fully research the analytical techniques used in documenting open literature studies, the Agency assumes that the methodologies employed by the National Oceanic and Atmospheric Agency comply with rigorous testing methods. The inability to completely resolve isomers does not negate the fact that endosulfan residues were detected.

ETF Comment: This reference [to endosulfan residues in mussels] needs at least a qualifying statement. The author states "The two components endosulfan I and II are not always chromatographically resolved from other analytes with the methods used in this study and therefore their detections at low concentrations was not reliable."

Agency Response: The information on endosulfan residues in mussels contained within the Wade et al. 1998 reference is from peer reviewed literature and was generated by the National Oceanic and Atmospheric Administration. The inability of the investigators to completely resolve endosulfan isomers via chromatography does not detract from their observation that endosulfan residues in mussels were orders of magnitude greater than exposure concentrations resulting in both chronic and acute toxicity to oysters.

ETF Comment: While EPA proposes that "incident data suggest phytotoxicity under certain conditions" the database does not provide more information if lettuce was both the application target and the species affected. The listing in the incident database only constitutes a claim, but no established cause and effect. Effects may have been caused e.g. by insufficiently cleaned spray equipment after herbicide application. Until more details of these incidents are known, the sentence should be deleted.

Agency Response: The Agency believes that data is a reliable indicator of the impact of the use of endosulfan on aquatic organisms. The fact that incidents have been reported after voluntary application restrictions were implemented, supports the Agency's concern that impacts to non-target animals are possible even when a 300-ft buffer is in effect. As reported in Appendix G of the assessment, a total of 4 incidents were reported involving plants. One incident involving safflower was a result of the registered use (aerial spray drift) and endosulfan residues were detected among the 2,000 plants killed. In two of the three remaining incidents involving lettuce, endosulfan residues were detected; however, the cause of the incidents was not determined. Although considerable details were lacking on the incidents associated with plants, there is sufficient information to conclude that on several occasions, endosulfan use was implicated in the death (phytotoxicity) of lettuce and safflowers.

(3) Consideration of Current Mitigation / Stewardship Efforts and the Runoff Buffer

ETF Comments: Incident reporting does not reflect the widespread improvement in recent years with revised use directions and improved stewardship.

This statement [incident data confirm the assessment that endosulfan use represents a serious risk of mortality for aquatic species] is not justified. After the change in application rates (maximum of 3 lbs a.i./Acre per year) and incorporated label mitigation measures (especially in California), the incident database does not confirm EPA's concern regarding risk through endosulfan registered uses.

Agency Response: As noted in the risk assessment, fish-kill incidents continue to be reported at a frequency similar to that of the early 1980's, prior to when the label changes and stewardship program were implemented. This frequency of incidents provides the greatest evidence that endosulfan continues to be present in water at concentrations that are sufficient to result in mortality to aquatic species.

ETF Comments: The current runoff buffer was not included in the assessment.

The ETF does not believe that it is appropriate to define the surface water label advisory at this time whilst many of the conclusions made by the Agency have been challenged by the ETF. The ETF believes that appropriate language already exists on end-use product labels, which include the need for a 300-foot buffer. Modifications to advisories should be drafted at the conclusion of the risk assessment and management process.

The ETF has presented a systematic modeling effort that included scenario selection, model input parameters sensitivity analysis and calibration and validation of buffer simulation that yielded exposure estimates that we consider to be realistic worst case scenarios. The risk quotients calculated by EPA resulted from unrealistic exposure estimation. They have no relevance to realistic worst case conditions as no attempt has been made to account for the effect of the label requirement for a 300 foot buffer on runoff. The buffers were established as exposure mitigation requirements in the labels not only for reducing spray drift, but also runoff. The effect of the 300-ft buffer on runoff reductions was not considered in EPA's refined risk assessment leading to a skewed conclusion. Several studies found in the literature and the studies submitted by ETF indicate significant reduction of exposure concentrations through runoff and spray drift caused by the effectiveness of a buffer strip.

This statement [spray drift buffer is not reflected in many of the end-use labels] is wrong. The use labels for all ETF products include the language for a 300-foot buffer to minimize runoff and spray drift. It does not limit exposure to only drift but effectively mitigates also runoff.

This statement [buffer is not specifically designed to be a runoff deterrent] is not true and should be deleted. The buffer zone outlined on the label was also established to minimize runoff. A buffer width of 300 feet (. 100 m) is very substantial. This mitigation measure was incorporated into the ETF end-use labels to minimize spray-drift and runoff and was mutually agreed to by the EPA at the time of introduction. Several studies found in the literature show that a vegetative buffer of this magnitude will substantially reduce transport of agricultural chemicals to the water body. The studies conducted by the registrants (MRID# 41309701 and 44903601) show a reduction of up to two orders of magnitude in endosulfan loads as a result of a 200-ft buffer.

It is a well-established fact that the vegetative buffers reduce sediment loading to water bodies and literature supports this. Recent researches reveal that buffers also mitigate transport of agricultural chemicals through runoff. Studies submitted by the ETF (MRID# 41309701) further confirm these results. The exposure assessment submitted by the ETF in October 1999 (MRID# 44953103) used PRZM to simulate endosulfan loading reduction to the water body. The modeling work was calibrated and validated using the field data from MRID# 41309701 and demonstrated a reduction of 60 – 90% of total endosulfan loading through runoff by the buffer. This proves that the effectiveness of vegetative buffers on runoff reduction can be quantified. ETF respectfully requests the EPA to consider the submitted exposure assessments.
As outlined in several responses above, buffer zones will also reduce runoff, significantly. As a consequence EEC values will be significantly lower with a concomitant decrease in risk quotients. Therefore, the likelihood of exceeding acute or chronic LOCs will be reduced, as outlined in ETF's submitted risk assessment (MRID# 44903601). The 300 ft buffer also impacts runoff, which needs to be considered in the calculation of EECs.

Agency Response: The labels state: "Due to the risk of runoff and drift, do not apply within a distance of 300 feet of lakes, ponds, streams and estuaries." This language began appearing on the labels in 1992 and the Agency has revised its risk assessment to reflect this. However, it is important to note that the language specifies only a 300-foot setback from the specified water bodies and does not specify a vegetative buffer. The Agency's reasons for not considering potential runoff effects in the assessment include:

- A spray drift buffer is not necessarily a runoff buffer, which involves more than shifting the application area 300 feet from the target. A runoff buffer must be specifically designed to reduce runoff and must be permanently planted in vegetation and properly maintained (see, for example, the USDA NRCS publication **Conservation Buffers to Reduce Pesticide Losses**, March 2000). The label does not specifically mention runoff buffer designs or the need to properly maintain the buffers.

- Runoff buffers are effective with sheet flow (which is roughly uniformly distributed) and not with concentrated flow, such as erosion channels, rills, and gullies. Thus, if not maintained, the buffer will not be effective (USDA/NRCS, 2000 publication).

- The 1999 Kentucky runoff study submitted by the ETF (see comments below) showed that the runoff buffer was not always effective.

A measure of the effectiveness of the stewardship efforts and label changes, including the 300-

foot buffer, comes through an evaluation of the frequency of incidents since mitigation went into effect. As noted earlier, the frequency of fish-kill incidents shows no sign of declining as a result of endosulfan use. This evidence indicates that the buffer is not performing effectively, at least not in all places in all years.

ETF Comments: Please add the runoff study performed in Kentucky,1999 (MRID# 44903601). An additional runoff study was conducted in South Carolina in 1989 (MRID# 41309701) with a 200 foot vegetative buffer strip. This study demonstrated that a vegetative buffer (200 ft) can reduce the Endosulfan concentration in the runoff by two orders of magnitude.

The results of the South Carolina runoff study (MRID# 41309701, Mester, 1989), which actually had a 200ft. vegetative buffer, as well as the Farm Pond study without a buffer (MRID#41164101; Cornaby,1989) are not presented in this chapter. The S. Carolina study was reviewed by the Agency (1/11/93; H. Nelson) and considered technically strong in many ways, but not sufficient to fulfill the guideline requirement, mainly because of the chosen soil type, application technique (aerial instead of ground) and slow irrigation rate.

Agency Response: The 300-foot buffer may in some instances provide the added benefit of reducing the amount of endosulfan that reaches nontarget aquatic environments. However, as noted in USDA publications, the runoff reduction benefits require a properly designed and maintained vegetative buffer, something not specified in the current label language. In addition, the ETF's runoff study in Kentucky showed that the buffers are not as effective as expected. The risk characterization will note that, in some instances, the 300-foot buffer specified on the label may have the added benefit of reducing endosulfan concentrations in runoff water. In addition, the Agency notes that multiple yearly fish kill incidents continue to occur in the years since the label revisions and stewardship efforts were put into place.

The 1999 Kentucky study is discussed in the "Runoff" section of the Agency's risk assessment and the MRID reference will be added. While the 1989 South Carolina study was considered technically strong in many ways in a 1993 review, the Agency concluded that the applicability was limited because the chosen soil type was not particularly vulnerable to runoff and the irrigation used to simulate rainfall was not applied at a rate sufficient to generate significant runoff. In addition, data and results were not clearly presented. These flaws are such that the effectiveness of a buffer could not be assessed.

(4) Characterization of Endosulfan as an Endocrine Disrupter

ETF Comments: Endosulfan is constantly implied to be an endocrine disrupter or considered a reproductive and developmental toxin, which is clearly the opposite of HED's conclusions. Only in-vitro studies indicate a low affinity of endosulfan to the endocrine receptors. In-vivo studies including a vitellogenin study in fish indicate that there is no endocrine disruption by endosulfan (Heusel, 1999; MRID# 45218801). A more detailed response can be found below responding to Appendix K. This statement is misleading and should be deleted. In the HED Risk Assessment for Endosulfan RED document (Barcode D250471, 2/17/00), it was stated that HED has thoroughly evaluated data on the developmental and reproductive toxicity of endosulfan in mammals. HED determined that endosulfan was not a developmental or reproductive toxicant, and concluded: "The data base is complete and there are no data gaps pertaining to developmental or reproductive toxicity. The data provided no indication of increased sensitivity of rats or rabbits to in utero and post-natal exposure to endosulfan." Based on the complete database, HED stated again, in the Executive Summary, that "Results

from development and reproductive toxicity studies conducted under OPPTS guidelines do not show increased or special sensitivity of the fetus or offspring to the toxicity of endosulfan."

While endosulfan has been shown to have very weak estrogen binding potential in in vitro screening assays, scientific groups such as the Endocrine Disrupting Screening and Testing Advisory Committee (EDSTAC) and the OECD Task Force for Endocrine Disrupter Testing and Assessment (EDTA) have emphasized that this type of screening data has limited predictive capabilities. Therefore, before a definitive finding of endocrine disruption can be made, evaluation through in vivo screening and testing must be conducted and a weight-of-evidence determination concluded from all available data.

In addition, the data cited used assays that have been determined to be too unreliable for regulatory screening purposes, and the results have not been supported by data generated from a multitude of valid in vivo screening and testing methods. As stated by HED, until EPA has completed the development of criteria for the evaluation of endocrine disruption, the classification of a chemical as an endocrine disrupter is scientifically inappropriate. The ETF strongly believes that a full evaluation of available data for endosulfan will clearly show that endosulfan is not an endocrine disrupter.

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Endosulfan is not mutagenic in mammalian cells. HED evaluated the available data for endosulfan for mutagenic potential and concluded the following: "Endosulfan was not carcinogenic and did not show any [emphasis added] mutagenic potential. There was no increase in the frequency of tumors in either the rat or mouse carcinogenicity studies. Endosulfan is classified as a Group E carcinogen (evidence of non-carcinogenicity for humans) by the Agency. The submitted mutagenicity studies have satisfied the data requirements for mutagenicity testing, and there is no concern for a mutagenic effect in somatic cells. In the in vitro or in vivo mutagenicity studies, both the mouse lymphoma forward mutation assay and the unscheduled DNA synthesis assay were negative" (P. 3 HED Toxicology Chapter for the RED). In addition, hematological effects noted in subchronic and chronic studies were secondary to the direct cytotoxic effect of endosulfan on the liver and spleen, and were not associated with genotoxicity. HED determined that the guideline data is complete, reliable and conclusive, clearly showing that endosulfan is not mutagenic in mammalian cells. Therefore, while data from public literature should be acknowledged and evaluated for scientific merit, the implication that this data is conclusive is misleading and inappropriate.

The ETF respectfully request that this statement be removed or that HED's conclusions be included in the discussion of mutagenicity for endosulfan. The ETF also recommends that all available data on mutagenicity in non-mammalian species be evaluated prior to making a final determination. Using a single reference to a non-guideline study, without evaluation of the entire database, is scientifically inappropriate. Endosulfan does not act as an endocrine disrupter in in-vivo studies. At this point, until EPA has fully evaluated all relevant data and argumentation, and until the criteria are established for classifying a compound as an endocrine disrupter, a reference to an alleged endocrine disruption potential should be deleted.

Agency Response: In several areas the Endosulfan Task Force has suggested that the Agency's EFED and HED Division's were not consistent with their interpretation of endosulfan's potential to act as an endocrine disrupter. Both Divisions maintain that available literature supports the Agency's concern that endosulfan is a potential endocrine disrupter.

In a memo (DP Barcode D270808) from the Health Effects Division dated December 11, 2000, the Agency responded to the Endosulfan Task Force's contention that endosulfan does not meet the definition of an endocrine disrupter. In the response, the Agency identifies an environmental endocrine disrupter as an exogenous agent that interferes with the synthesis, secretion, transport, binding action, or elimination of natural hormones in the body that are responsible for the maintenance of homeostasis, reproduction, development, and/or behavior.

Based on these criteria, the Agency disagrees with the conclusion by the registrant that endosulfan does not meet the definition of an endocrine disrupter. Binding to the estrogen receptor is only one potential mode of action for endocrine disrupters, namely direct interaction with a receptor in the target cells.

Substances that act as endocrine disrupters may perturb the endocrine system in a variety of way including but not limited to interfering with the synthesis, secretion, or transport of hormones in the organism. Consequently, the absence of high binding affinity to the estrogen receptor should not be interpreted as lack of endocrine disrupter potential.

In response to the registrant's comments that no effects were reported after administration of endosulfan on the endocrine, reproductive or sexually regulated systems at doses causing clear toxicity, the Agency cited testicular atrophy and increased incidence of parathyroid hyperplasia

observed in chronic oral toxicity studies of rats (MRID 00004256) and increased pituitary and uterine weights observed during multi-generation reproduction studies (MRID 11148264) as clear reproductive effects. Given the effects noted in the mammalian studies, the Agency's Health Effects Division could not discount the potential of endosulfan to act as an endocrine disrupter.

In the revised human health assessment, endosulfan is identified as a potential endocrine disrupter. The potential for endosulfan to cause changes in endocrine function that lead to adverse effects was evaluated from the results of the submitted guideline studies and available published studies and endosulfan was identified as a potential endocrine disrupter. The Agency is in the process of developing criteria for characterizing and testing endocrine disrupting chemicals and plans to implement an Endocrine Disrupter Screening Program in 2001. Endosulfan will be reevaluated at that time and additional testing may be requested.

Additionally, the ETF has commented that *in vitro* studies should not be used to support the notion of endosulfan as a potential endocrine disrupter. While *in vitro* data strongly support claims that endosulfan is an endocrine disrupter, there is also sufficient *in vivo* data to support the Agency's concerns for endosulfan's endocrine disrupting potential. Exposure to endosulfan has resulted in both reproductive and developmental *in vivo* effects in nontarget animals beyond those identified in the human health risk assessment. Tadpoles exposed to endosulfan exhibited significantly higher post-exposure mortality (Berrill *et al.* 1998), impaired development, and failed to metamorphose. The study concluded that at concentrations likely to be encountered in the environment, 2-week-old tadpoles exhibited greater sensitivity of post-hatching development of the neuromuscular system. Additionally, studies on the intersexuality of the genital system in birds revealed that endosulfan impaired the development of the avian genital tract (Lutz and Lutz-Ostertag 1975). Chronic toxicity test result using EPA guideline avian reproduction studies reveal treatment-related effects on reproductive parameters (reduction in the number of eggs laid and hatchability). Based on data from both in vitro and in vivo studies in aquatic and terrestrial organisms, The Agency's concern for endosulfan's endocrine disruption potential is well supported and is consistent with the concerns raised in both the human health and ecological risk assessments.

Finally, the available scientific literature indeed supports the Agency's conclusions regarding the possible endocrine disruption/reproductive effects of endosulfan. In addition, both assessments are now in agreement regarding the possible endocrine disruption effects of endosulfan. The ETF cites literature indicating that exposure of fish to endosulfan did not result in the induction of vitellogenesis, a common bioindicator for estrogenic effect. The ETF did not consider available literature indicating that in fish, endosulfan may serve to down-regulate the vitellogenin gene and result an inhibition of vitellogenesis; thus, in fish, endosulfan may be antiestrogenic but still indicative of an endocrine disrupting effect.

(5) Use and Interpretation of Surface Water Monitoring Data

ETF Comments: Monitoring studies do not confirm a widespread contamination of surface water or ground water from current US labeled uses.

This sentence [monitoring confirm widespread contamination of surface water] should be deleted, since a "widespread" contamination is not confirmed if all data are properly evaluated.

Agency Response: While the STORET database contains some inconsistencies, it does indicate that endosulfan has been found in surface water in each of the states where it has been used. There is no indication from the available monitoring data, incident data, or the ETF's comments

that this has changed.

ETF Comments: The surface water monitoring results after the introduction and implementation of use restrictions (between 1988 and 1993) show significantly lower concentrations of endosulfan residues in surface water that are well below the contamination level (MCL). A detailed analysis is presented in Appendix 1. . The results of analysis of surface water monitoring databases (STORET, USGS-NAWQA and CA-DPR) show no evidence of "widespread contamination".

The range of monitoring data considered in the comparison includes data prior to the introduction and implementation of use restrictions (1990). Appendix 1 shows that in surface water monitoring records (STORET, NAWQA and CA-DPR Surface Water Database) show significantly reduced levels of the endosulfan concentrations in surface water after the introduction of use restrictions. The exposure concentrations estimated by EPA compare more closely with the monitoring data (STORET) data prior to the introduction of use restriction (1990), but not to the data after 1990 (Appendix 1).

On the other hand, the exposure concentrations estimated by the ETF (MRID# 44953103) are generally higher than the monitored values, but are within realistic magnitude of the monitoring data after 1990. This further compels the necessity of considering the effect of buffer on runoff in the exposure estimations.

EFED had analyzed all the available monitoring data in STORET in a lumped manner. However, it should be analyzed in chronological manner. This will highlight the effect of the introduction of the label restrictions on the levels of endosulfan detected in the surface waters. See Appendix 1 for a chronological analysis of STORET monitoring data, which shows that the introduction of use restrictions resulted in significantly lower concentrations and in most cases that no endosulfan residues were detected in surface waters.

Agency Response: Endosulfan does not have an established MCL. The trends the ETF point to in their analysis of STORET data are difficult to support because no monitoring data was conducted to specifically investigate the impact of the use restrictions on endosulfan concentrations in water. STORET is a mix of monitoring data collected at different sites, at different times, at different levels of detection, and for different purposes. As a result, STORET monitoring data cannot be grouped together for trend analysis such as that done by the ETF. Further, the Agency is unable to draw conclusions as to whether endosulfan residues in water have been "significantly" lowered or whether such trends are the artifacts of combining data.

ETF Comment: The latter part of this statement [endosulfan is susceptible to transport via runoff for prolonged periods after initial application] is not correct, when it comes to quantitative assessments. As already stated earlier in HED's drafted risk assessments (under Monitoring Data: 4.3.b.2; page 35) it was stated: "The monitoring data indicate, however, that EFED's simulation models tend to overestimate actual concentrations of Endosulfan residues in surface and groundwater". Based on all available monitoring data for Endosulfan from various water treatment plants, most of the detects were between 0.009 and 0.6 ppb.

Agency Response: The Agency's human health risk assessment has been revised to reflect the latest drinking water characterization and that particular language, which is not reflective of the actual assessment, has been removed. Indeed, as noted in both the human health and ecological risk assessments, the modeled estimated water concentrations are well within the range of measured endosulfan concentrations in the EPA STORET database (where total endosulfan

concentrations range from less than the level of detection to a maximum peak of 180 µg/L).

It is important to distinguish between endosulfan concentrations at drinking water treatment plants and those found in ambient water in general. Given endosulfan's tendency to sorb to sediments, it is likely that flocculation/sedimentation and filtration processes that are typical in most surface water treatment processes will result in substantial removal of endosulfan residues suspended in water. This does not mean that endosulfan was never present in the water.

Given endosulfan's expected behavior in water (expected short duration time as dissolved endosulfan in water, with preferential sorption to bottom and suspended sediment), most monitoring studies are unlikely to detect the peak concentrations of endosulfan resulting from runoff unless sampling occurs at least daily or is specifically timed to coincide with runoff events. In addition, many analytical methods for water filter the samples (and thus would filter out any endosulfan in suspended sediments) and are not likely to reflect total endosulfan load in the water column. Acute mortality impacts occur from short-term exposure of aquatic organisms to endosulfan in water.
The reported fish kills are evidence that endosulfan is indeed getting into water at concentrations that are sufficient to result in mortality.

ETF Comment: Endosulfan was included in NAQWA program since the time of its initiation (1991). However, the monitoring results were not reported in the prior NAWQA reports. See Appendix 1 for an analysis of the monitored endosulfan data from the NAWQA database.

Agency Response: This statement and the presentation in the appendix need to be clarified. Endosulfan has not been included in the suite of chemicals USGS analyzed for in surface-water and ground-water samples [see http://water.wr.usgs.gov/pnsp/anstrat/ ; **PESTICIDES ANALYZED IN NAWQA SAMPLES: Use, Chemical Analyses, and Water-Quality Criteria**; USGS]. It was included in some sediment samples, and was not sampled in as widespread an area as the ETF implies by showing the map of the NAWQA study units [see http://water.wr.usgs.gov/pnsp/rep/sedbiota/ ; **Organochlorine Pesticides and PCBs in Bed Sediment and Aquatic Biota from United States Rivers and Streams: Summary Statistics; Preliminary Results of the National Water Quality Assessment Program (NAWQA), 1992-1998**; USGS]. The dissolved concentrations the ETF refers to in their response are from analyses of sediment. These concentrations are not relevant to concentrations in the water body that would result in acute toxicity from short-term exposures.

After an extensive analysis of the information provided by the ETF in its Appendix 1, the Agency believes that it has used and characterized the available monitoring data on endosulfan to the extent possible. However, the Agency has added language in its water assessment noting that, given endosulfan's expected behavior in water, monitoring data with infrequent sampling intervals is unlikely to detect the peak concentrations of endosulfan in water and that it is these concentrations that are most likely to cause the fish kills that are reported to the Agency.

(6) Characterization of the Persistence of Endosulfan and its Toxic Transformation Products

ETF Comment: The chemical's persistence was considerably over-estimated.

Agency Response: This characterization is based on the studies submitted by the ETF and on published scientific literature. As noted here and in the response in regarding PRZM/EXAMS modeling, the Agency believes it has accurately characterized the persistence of both isomers of endosulfan, as well as the toxic transformation product endosulfan sulfate.

ETF Comment: This statement [estimated half-lives of combined toxic residues ranging from 9 mo to 6 yr] is a misrepresentation of facts. Due to the limited size of the soil samples in the standard laboratory studies, the microbial activity decreases within 3 – 4 months. As a consequence, laboratory half-lives in long-term studies are frequently overestimated. Therefore, half-lives from field studies are more realistic. The combined endosulfan isomers and endosulfan-sulfate were found to degrade with overall half-lives ranging from 26 to 176 days based on the terrestrial dissipation studies submitted by the ETF (Hacker (1989,MRID# 41309702), Mester (1990, MRID# 41468601), and Czarnecki & Mayasich (1992, MRID# 43069701)).

It should also be added that the half-life for endosulfan sulfate of 300 to 2000 days was obtained under confined laboratory conditions (c.f. ETF response to the corresponding EPA comment on page 2).
This statement [dissipation of endosulfan in the field was within the same magnitude as would be predicted from laboratory studies] is only true with regard to the parent isomers. The degradation of the sulfate in the field is significantly faster than measured in the laboratory with the limited microbial activities in long-term studies. As a consequence, field half-lives should be used in the modeling in order to consider the exposure of the combined endosulfan residue of relevance (a, b and endosulfan-sulfate).

Agency Response*:* The Agency believes that the half-life values are calculated from actual laboratory data. As noted in the risk assessment, the laboratory half-life values for the parent isomers were on the same order as those reported in the field dissipation studies (with the exception of one site). Since lab studies characterize single routes of dissipation and the field study results represent a combination of dissipation factors, ranging from degradation to volatilization (not tracked in the study), movement by runoff (not tracked), and low recovery (an artifact of the sampling design and analytical procedures and not a true route of dissipation), the Agency would generally expect field dissipation rates to reflect a shorter total dissipation rate.

The field dissipation studies did not adequately track the pattern of formation and decline of endosulfan sulfate in order to quantify the half-life of that chemical. As material recoveries decline with time in the field dissipation studies, projected half-lives are subject to great error resulting from incomplete recoveries. Thus, the Agency's views the DT_{50} (time for 50% decline in initial concentrations) and DT_{90} (time for 90% decline in initial concentrations) values to be better characterizations of field persistence.

With regard to using field dissipation values in modeling, the current models use lab-derived values for specific routes of dissipation (i.e., photolysis, hydrolysis, metabolism, mobility) to simulate field dissipation. Thus, field dissipation half-lives are inappropriate inputs because, in addition to the flaws noted above, they would, in effect, double-count multiple routes of dissipation.

The Agency compared field dissipation study results to the predicted endosulfan concentrations in the surface soil over time, as modeled by PRZM, and found that the model was not overestimating endosulfan concentration. Indeed, the calculated field dissipation half-life using PRZM (147 days) was within the range of that measured in the field dissipation studies.

ETF Comments: Based on the results of field monitoring program results, endosulfan cannot be classified as persistent. Based on a number of publications not used by EPA, endosulfan is detectable only in very low concentrations in the air during the time of application and decreases

to extremely low levels during off-season. The extremely low traces occasionally found in remote areas were not confirmed in each reported case.

From monitoring studies (Tiirmaa & Dorn, 1988) covering different geographical areas and conditions it can be concluded that endosulfan does not accumulate in soil or form a concentration plateau of ecotoxicological relevance in soils even after extensive and consecutive use for several years under normal agricultural practices. The report will be submitted by the ETF.

Long-term field accumulation studies in different regions of the world (Tiirmaa & Dorn, 1988) have shown that endosulfan after yearly application of 5.5 to 12.5 kg/ha over a period of 5 to 7 years dissipates within 6 months after the last application to a total residue level of less than 0.1 ppm (soil 0-10 cm). There is no soil accumulation of endosulfan, even after excessively high application rates over many years.

Agency Response: The Agency has not been provided the particular reference mentioned by the ETF, so we cannot comment on its implications. If the ETF provides the reference and the Agency, upon review, determines that it provides new information not already covered in the risk assessment, then we will incorporate it into our assessment after the public comment period. However, the Agency notes that the half-life values for the total toxic residues reported in the field dissipation studies ranged from 3 to 6 months, a sufficient period for some carry over in subsequent years to occur.

ETF Comment: The reference to the PBT strategy is not necessary for the assessment, is misleading, and should be deleted. Endosulfan is not included in the two recent listings by EPA related to PBT chemicals (Final rule published on October 29, 1999 in Federal Register and the Press Advisory published on August 31, 2000 regarding EPA PBT Initiative). Endosulfan was included in the "proposed" list, for comments, by EPA/RCRA under the "Draft RCRA Waste Minimization PBT chemical List". As evident in the contents of the Federal Register Notice (11/9/98), the RCRA inclusion is solely based on a partial database of laboratory values (K_{OW}, BAF/BCF), and the use of these laboratory numbers to derive the justifying "scores" by the use of a computer modeling software (WMPT). Such approach ignores all other available ecobiology and environmental data conducted under actual field conditions. Collectively, these data show clearly that endosulfan does not bioaccumulate or persist in the active soil environment under actual agricultural and field conditions. ETF has since responded to the RCRA proposal and had provided the Agency with a complete data summary including those from worldwide field-testing. Endosulfan was not listed as a result of considerations of realistic conditions. It is apparent that EFED did not consider the statements contained in other sections of the review where rapid depuration of observed bioaccumulated residues in the relevant studies was cited. Therefore, the Agency should delete the reference to PBT or add a qualifying statement like "However, depuration studies conducted in fish suggest that endosulfan residues do not bioaccumulate under natural conditions."

Agency Response: The Agency believes the persistence of endosulfan is accurately characterized in the risk assessment. When mobile routes of dissipation are taken into account, the net dissipation rate from the soil surface predicted using laboratory inputs is consistent with those measured in the field dissipation studies. Except for minor revisions as noted, no changes were made to the risk assessment regarding the persistence of endosulfan and its combined toxic residues. The section on PBT (Persistent-Bioaccumulative-Toxic) was included because the Agency did consider endosulfan as a potential PBT candidate. One action plan noted that such a

determination could be made as a part of the re-registration process. While endosulfan would likely meet the toxic and persistent criteria, its rapid depuration in fish suggest that it would probably not meet the bioaccumulative criterion. Thus, that section noting this to be the case will be revised.

(7) Ground Water Advisory Statement

ETF Comments: Monitoring studies do not confirm a widespread contamination of surface water or ground water from current US labeled uses.
The ETF does not believe that this proposed Groundwater Advisory is appropriate. Endosulfan has not exhibited mobility in field studies that warrants such an advisory and it is strongly adsorbed to soil particles.

This statement [on endosulfan being detected in wells] is misleading, of very qualitative nature, and should be rephrased. If one evaluates the total numbers in the available surveys (USEPA, 1992), the number of positive detections are insignificant (1.3%), as well as the concentrations range from <0.005 to 20 ppb. Again referring to HED's recent risk assessment (under Monitoring Data: 4.3.b.2; page 35), it was stated that "an analysis of the EPA STORET database conducted in 1985 showed that of 850 well water samples analyzed, none contained detectable residues of endosulfan sulfate". The ETF will provide a further response to this comment during the 60-day comment period.

The ground water detection reports (Pesticides in Ground Water (1997-91) should be viewed on a qualitative basis.

Agency Response: The Agency agrees that widespread contamination of ground water with endosulfan is not expected to occur. The overall assessment did not emphasize endosulfan occurrence in ground water. Endosulfan did not exhibit the characteristics normally associated with those pesticides that are frequently detected in ground water. However, endosulfan has been detected in some wells and, in the water resource assessment, the Agency described the conditions under which such movement to ground water are likely to occur. No mitigation measures were discussed in the risk assessment. The recommendation for a label advisory for ground water, found in the transmittal memo to SRRD, was based on the fact that some detections of endosulfan did indeed occur. However, the main concerns are not with endosulfan in ground water. The transmittal has been revised to clarify this point.

ETF Comment: The reference to a Spanish groundwater monitoring report is inappropriate and should not be used for an US EFED assessment. The circumstances of the findings are not known. Use conditions and environmental awareness are different from the conditions in the US.

Agency Response: The reference to endosulfan detections in ground water in Spain is found in one of the appendices. The Agency did not use the reference in its water assessment. The Agency agrees that the results of this study need to be considered in context with site and use data to determine the extent to which the results may apply to conditions in the United States. Until such supporting information can be obtained, the reference will be deleted.

(8) Characterization of the Fate of Endosulfan in Water

ETF Comment: This statement [regarding slow release of endosulfan back into water] should be deleted. Barry and Logan (1998) speculated: "Dying plant species may have also been an important source for the slow release of endosulfan back into the microcosms", but did not offer any proof. The release of absorbed endosulfan from dying macrophytes was not investigated in this study. The concentration of endosulfan measured in the microcosms follows a smooth decline pattern and did not suggest slow release into water phase from any adsorbed source. The study notes that only 6 to 12 % of the applied endosulfan (as endosulfan and endosulfan sulfate) was present in the macrophytes at the end of the study. The study also notes that metabolism of endosulfan in the macrophytes and algae as significant route of degradation. Therefore, if there is a potential for endosulfan to be released back into water upon dying of macrophytes, the amount that will be available for release will be what is left from degradation in the macrophyte tissue and will be infinitesimal.

In this place, no reference is provided for the reversibility of this process. This statement is presumably based on Barry and Logan (1998). It should be noted that release of absorbed endosulfan from dying macrophytes was not investigated in this study. A statement "Dying plant species may have also been an important source for the slow release of endosulfan back into the microcosms" stated in the paper is a speculative comment (see above for a more detailed ETF comment on this issue). Because of the speculative nature of the statement, the second half of the sentence should be deleted.

Agency Response: The assessment has been revised to note that the authors speculate that dying plants may have been a slow release source of endosulfan back into water.
This study was used in the characterization of endosulfan in the water column but was not key to the assessment. Thus, this revision does not change the risk assessment conclusions.

ETF Comment: In addition to the cited microcosm study the ETF also conducted a farm pond study in 1989 (MRID# 41164101; Cornaby, 1989), which was accepted by EPA fulfilling the Reference Guideline # 72-7b. This study was conducted under "worst case" conditions (did not reflect 300 ft buffer). We believe that the subject study is important for the EFED risk assessment. Very high concentrations of Endosulfan in the runoff water (>220 ppb) were diluted by a factor of 100 (peak concentration in the pond was 1.3 ppb). Only higher concentrations caused some fish kill in the shallow areas where the runoff entered the pond. By adding a "300 foot buffer" as presently on the label, these effects would likely have been totally mitigated. The pond study was reviewed (4/24/91; N. Cook) and found acceptable.

Agency Response: The pond study was found to be acceptable for its utility in the ecological assessment, but not necessarily for its utility in characterizing the fate of endosulfan in water. A subsequent review by H. Nelson found that it provided useful supplemental information. The conclusions of that review will be added to the ecological risk assessment. Among the conclusions, the study found that α- and β-endosulfan and endosulfan sulfate were detected in runoff water in all events through the last sampling date in November, at least five months after the last application.

The dilution factor going from runoff to pond will be a function of the volume of runoff and the size of the pond. Thus, generalizations based on a single study are suspect. The existing models used by the Agency already take the dilution into account.

(9) PRZM/EXAMS Model Inputs

ETF Comments: The endosulfan exposure assessment conducted by the EPA using PRZM/EXAMS modeling does not reflect realistic use conditions and scenarios. The risk quotients resulted from unrealistic exposure estimation. They have no relevance to realistic worst case conditions. Two of the chosen scenarios not addressed (lettuce in Tennessee and grapes in New York) are not representative of the use of endosulfan in these crops. The ETF has presented a systematic modeling effort that included scenario selection, model input parameters sensitivity analysis and calibration and validation of buffer simulation that yielded exposure estimates that we consider to be realistic worst case scenarios. The risk quotients calculated by EPA resulted from unrealistic exposure estimation. They have no relevance to realistic worst case conditions as no attempt has been made to account for the effect of the label requirement for a 300 foot buffer on runoff.

This statement [non-conservative assumptions] is incorrect and should be changed. As pointed out above, the endosulfan exposure assessment conducted by the EPA using PRZM/EXAMS modeling does not reflect realistic use conditions and scenarios.

If EPA would use truly non-conservative assumptions (e.g. considering the 300 ft runoff buffer, field half-lives etc.) the conclusions presented in the paragraph would NOT result in unacceptable risks.

As the runoff buffer was not considered, PRBEN numbers were unrealistically low, laboratory soil dissipation rates were used and degradation rates from aerobic aquatic/sediment studies were ignored, the assessment is still a conservative one.

The assessment of "high risk" should be deleted as it is only based on unrealistic assumptions disregarding e.g. runoff buffers. Refer to risk assessments submitted in October, 1999 by ETF (MRID# 44953101, 44953102, 44953103).

The ETF exposure assessment using realistic use conditions and current label mitigation such as 300 ft buffer zones (MRID# 44953102 – 04) shows that endosulfan poses a low risk to aquatic organisms.

Agency Response: The Agency will make appropriate additions to the characterization of the endosulfan risk. The Agency has also noted that field dissipation half-lives are inappropriate inputs for PRZM/EXAMS. However, a comparison of PRZM simulations of endosulfan dissipation from the soil surface to measured dissipation rates in the field studies shows that the ecological risk assessment does not overestimate endosulfan dissipation.

ETF Comments: The label rate for lettuce is 3 x 1.0 lb. a.i/A instead of 2 x 1.5

The used crop application rates and numbers are not correct for lettuce (label states 1 lb./A, 3 applications) instead of 1.5 at 2 applications. For potatoes the label states 1 lb/A at 3 applications instead of 3 lbs/A once. The change of these input parameters will effect the results of the acute and chronic RQs.

The highest single application label rate for lettuce is 1.0 lb a.i./Acre.

Agency Response: The ETF statement regarding application rates for lettuce appears to be true only for the EC formulations. According to the most recent labels EFED has for Phaser 50WSB

(EPA Reg. No. 45639-194, 45639-198, dated 3/8/2000), Thionex 50WP (66222-02, 4/8/1995), and Thiodan 50WP (279-1380; 9/3/98), the maximum single application rate can be 1.5 to 2 lb a.i./A for lettuce, with 2-3 applications per year and a maximum yearly rate of 3 lb a.i./A. Thus, the Agency's screening model rates reflect label rates for lettuce. The maximum single application rates found for potatoes is 2 lb a.i./A with a yearly total of 3 lb a.i./A (Reg. No. 66222-02, 4/8/95; 45639-194; 3/8/00; 279-1380; 9/3/98). For the aquatic exposure assessment, EFED modeled an application rate of 1 lb a.i./A., as noted in Table 3.
The information on applications provided in Tables 14 and 15 are in error and will be corrected (the estimated concentrations reported in that table are the result of 3 applications of 1 /b a.i./A each). In addition, the refined aquatic risk assessment modeled typical application rates and not the maximum label rates.

Tables 11 and 12 in the terrestrial exposure assessment did include a single 3 lb a.i./A application for potatoes. The Agency has recalculated the terrestrial RQ values using a maximum single application rate of 2 lbs a.i./A and revised those tables. The conclusions of the risk assessment are unchanged given that acute high risk, restricted use, and endangered species LOCs are exceeded.

ETF Comment: As noted by EPA, these scenarios do not represent major crop/use areas. This is just not a conservative assumption, but will produce unrealistic exposure estimates. It should also be noted that endosulfan use in grapes represents a small portion of the total use. Therefore, the grapes exposure scenario should not be considered and the lettuce scenario should be revised using a more appropriate use area.

Agency Response: The Agency has selected a range of scenarios that included both major uses and a representation of the extent of different use patterns. Thus grapes were selected because that use is not reflected in other scenarios. The grape scenario did not result in the highest estimated water concentrations and does not unduly influence the risk assessment. A statement will be added that notes endosulfan use on grapes represents a small portion of total use. The Agency has already noted in the risk assessment that the lettuce scenario does not represent a major endosulfan use area.

ETF Comment: EPA assumed the aerobic aquatic half-life to be 2 times longer than the aerobic soil half-life. This is not correct particularly for endosulfan, which is readily hydrolyzed in water. The aerobic aquatic studies submitted by the ETF (MRID# 44917801 and 44917802) were deemed supplementary studies by the EPA. Therefore, the degradation rate (T½ for a- and b-endosulfan = 12 to 15 days and for total a-, b- and endosulfan-sulfate = 18 to 21 days) in the total sediment/water system from the above study should be used in the PRZM/EXAMS modeling.

Agency Response: Because no valid aerobic aquatic metabolism study was available, EFED used a default assumption for the aerobic aquatic metabolism rate. This assumption is not necessarily conservative, since aerobic aquatic metabolism rates for some pesticides proceed at an even slower rate than half the soil metabolism rate. It is also important to clarify here that hydrolysis is the decomposition of a chemical compound by reaction with water not metabolism and that the hydrolysis rate has been used in the model. Additionally, endosulfan only "readily" hydrolyzes in alkaline water; the rate is slower in neutral and acidic water. The model simulates the combined routes of dissipation of endosulfan in the water body by taking into consideration the combined degradation processes (photolysis and hydrolysis, which were based on actual studies, and metabolism, which is an estimated value) and transport processes (volatility,

adsorption to sediment). The studies referred to by the ETF were deemed supplemental because they were conducted under neutral to alkaline conditions that favored hydrolysis. Given that they did not distinguish between hydrolysis and metabolism, the studies do not provide a valid metabolism rate constant to use in the model.

ETF Comment: ETF still believes that a PRBEN value of 0.5 for a compound like Endosulfan (having a high Koc) is inappropriate. If there is any relevant recent literature available as stated by EPA addressing this, it should be quoted in the document. We contest that a value of 0.9 is more appropriate based upon results of microcosm studies with similarly lipophilic compounds. EECs calculated by PRZM/EXAMS are extremely sensitive to changes in this parameter.

Agency Response: The microcosm studies referred to by the ETF were not specific to endosulfan.

ETF Comment: The method adopted by EPA to calculate endosulfan sulfate EECs based on the ratio of endosulfan sulfate to a- and b- endosulfan in monitoring data is not appropriate. Endosulfan sulfate is a metabolite of a- and b-endosulfan and is formed as a result of the degradation. EPA's methodology of estimating endosulfan sulfate EECs would violate the mass balance of the endosulfan residues in the system in certain situations. This will particularly be true in the case of peak EECs. Therefore, ETF respectfully requests EPA to consider the exposure assessments (MRID# 44953101, 44953102, 44953103) for risk assessment.

Agency Response: The Agency used the method for estimating the combined endosulfan and endosulfan sulfate concentrations only as a screening estimate for drinking water concentrations to be used in the aggregate exposure assessment. Since the screening estimates did not exceed the DWLOC values, no further refinements in the drinking water estimates were needed. The aquatic ecological exposure assessments do not include endosulfan sulfate. Thus, the toxicological contribution of endosulfan sulfate (delivered to the water body in runoff from the field) is not included as a contributing factor to aquatic impacts.

ETF Comments: The EECs should be recalculated. EFED calculated these without considering the effectiveness of the 300-ft runoff buffer and the available field dissipation rates. A number of sensitive parameters chosen by EFED in their exposure assessment are unrealistic and inappropriate:

- In the cotton scenario the curve numbers used were inappropriate. A curve number of 99 would yield higher runoff than from a farm road (PRZM manual Curve Number Table).
- Instead of a PRBEN value of 0.5 for a compound like endosulfan (having a high Koc), a value of 0.9 is more appropriate. If there is any relevant recent literature available as stated by the EPA addressing this issue, it should be quoted in the document.
- Aerobic Aquatic Metabolism Half-Life: EPA assumed the aerobic aquatic half-life to be 2 times longer than the aerobic soil half-life (114 days for a-endosulfan, and 416 days for b-endosulfan). This is not correct, particularly for endosulfan, which is readily hydrolyzed in water. The aerobic aquatic studies submitted by the ETF (MRID# 44917801 and 44917802) were deemed as supplementary studies by the EPA. Therefore, the degradation rate (T½ for a- and b-endosulfan = 12 to 15 days and for total a-, b- and endosulfan-sulfate = 18 to 21 days) in the total sediment/water system from the above study should be used in the PRZM/EXAMS modeling.

Agency Response: The Agency believes that the issues raised by the ETF are the result of differences in interpretation of data and not factual or scientific errors. Thus, no revisions to the estimated endosulfan concentrations in water are being made at this time.

(10) Surrogate Species / Representativeness of Aquatic Community / Striped Bass

ETF Comments: The reference to the sensitivity of the surrogate species should be deleted. The use of "surrogate species" is standard practice in all ecotoxicological testing and risk assessment.

The use of "surrogate species" is standard practice in all ecotoxicological testing and risk assessment. For this reason EPA uses safety factors (or Levels of Concern) in the calculation of Risk Quotients. The reference to the sensitivity of the surrogate species should be deleted.

This statement [refined assessment affecting the aquatic system as a whole] needs to be rephrased, as the selection of species (fish, some invertebrates) cannot represent an "aquatic system as a whole". The selected species are not only limited, but also are selected for the higher sensitivity. One must assume that the sensitivity of organisms in an aquatic system is distributed in a similar way as the sensitivity of the large number of test organisms spanning several orders of magnitude.

Agency Response: The use of surrogate species as standard practice does not negate the position that these surrogates may not represent the most sensitive organisms.

ETF Comments: The values for the Striped Bass (0.1 ppb acute and 0.01 ppb chronic) should be deleted, as it results from a study that is rated "INVALID; temperature fluctuations too great" in the reference list on page 108. The more appropriate study to cite here is the Striped Mullet (LC50= 0.38 ppb; see p.93; MRID# 40228401). This study is classified as core.

As a consequence of replacing the values for the Striped Bass with those from the Striped Mullet, the sentence should read now: "Acute aquatic toxicity estimates ranged from 0.38 to 166 ppb for endosulfan."

The LC50 of 0.1 mg/L for Striped Bass is taken from an "invalid" study. It would be more appropriate to use a value from an acceptable (core or supplemental study), e.g. the Striped Mullet LC50 of 0.38 mg/L (MRID#40228401). As a result all listed acute and chronic RQs would change, if a more appropriate EEC was calculated (see earlier comment about the use of PRZM/EXAMS).

Agency Response: The striped bass study (MRID 40228401) was conducted by the U.S. Fish and Wildlife Service (USFWS) in 1980. In the review, the USFWS concluded that the study could not meet core guideline requirements because of temperature fluctuations; however, the study was not formally classified as invalid. It is Agency policy to accept USFWS studies as supplemental. The study was incorrectly identified in the draft assessment as invalid; however, the risk assessment has been updated to reflect the supplemental status of this study. Thus, the acute and chronic endpoints for estuarine/marine fish, *i.e.*, striped bass, remain as 0.1 µg/L and 0.01 µg/L, respectively. Additionally, the Agency has data which indicate that the LC_{50} to spot (*Leiostomus xanthurus*) may be as low as 0.09 µg/L (Schimmel, S. C., J. M. Patrick, and A. J. Wilson 1976. Acute toxicity to the bioconcentration of endosulfan by estuarine animals, Proceedings of the ASTM Symposium on Aquatic Toxicology, Memphis); therefore, the striped

bass acute toxicity estimate is not unreasonable. It is noteworthy however, that more refined assessments of risk were not based on the striped bass endpoint alone but rather a distribution of freshwater fish toxicity endpoints was used, which were an order of magnitude less sensitive than endpoints for estuarine/marine species.

(11) Terrestrial Exposure Values

ETF Comment: Instead of theoretical calculations based on Hoerger & Kenaga modified by Fletcher, actual plant residue values should be used. The ETF submitted in 1987 (MRID# 40261301) a risk evaluation of endosulfan to avian species including product specific plant residue data and its crop specific half-lives (123 trials from 18 different crops). This response was submitted in support of the revised maximum label rate (3 lbs./A/year). Assuming a NOEL of 30 ppm (Mallard Duck Reproduction) and given the crop specific half-lives (2.2 to 4.5 days) for total endosulfan measured at day of application (93 ppm) and two weeks thereafter (0.5 ppm) the risk to terrestrial organism is acceptable.

Agency Response: The Agency did not conduct a refined risk assessment for terrestrial organisms but rather relied on a screening-level assessment using exposure values based on the Kenaga nomogram, as modified by Fletcher. This approach is consistent with the screening-level assessment methodology used in the other Agency ecological risk assessments for pesticides. Should a revised terrestrial risk assessment be conducted, the Agency would consider the 1987 study data, as well as the contributing toxicity or exposure from endosulfan sulfate, which was not assessed in the study.

(12) Comparative Risk Assessment

ETF Comments: The comparison with five other chemicals considered to be alternatives was inappropriate and contrary to the Science Advisory Panels advice.

The comparative risk assessment should be deleted. The selection of competitor products seems arbitrary. Data input and assumptions are not transparent. The assessment performed does not take into account the full label restrictions on endosulfan. Neither the full pest spectrum of the competitors nor the benefits of endosulfan in Integrated Pest Management programs were considered. The computer model used for the comparison (DecideRight®) is a model for business decision. Its use in comparative risk assessment has not been validated. The SAP provided the following responses regarding the comparative risk assessment paradigm (Dec. 8-9, 1998):"Panel members believe there are too many scientific uncertainties in the approach to allow one to assume that the results do more than provide a rough estimate of relative, not absolute, risk within a narrow class of pesticide uses. The validity and use of the proposed approach (or a portion thereof) depends on the intended use of the results. It was not clear to the Panel how the proposed approach would be used within the existing regulatory framework. Therefore, it was difficult for the Panel to answer the specific questions below without knowing exactly how the calculations will be used and without having a clear statement of the limitations and assumptions that went into the risk calculations." "Several members of the Panel believe that comparisons of relative risk by simple combinations of RQs may not be meaningful." As detailed below, the Panel believes there are too many scientific uncertainties in the approach to allow one to assume that the results in fact quantify the true ecological risk. In addition, the assumption that all products are interchangeable is not always true."

Agency Response: The selection of alternative pesticides used in the comparative risk assessment was not arbitrary but rather was based on an Agency analysis by the Biological and Economic Assessment Division for likely alternatives as a function of crop and target pests.

The comparative risk assessment does not combine RQ values but rather their relative rankings. Additionally, the comparative assessment is not intended to be definitive but rather serves as a tool to aid the risk manager in gauging risks relative to alternative pesticides. The Agency believes that the Science Policy Panel conclusions regarding the comparative risk assessment indicate that the methodology for the comparative assessment methodology was reasonable for screening-level assessments provided that comparative assessments were limited to ranking based on RQ values rather than a mix of rankings based on RQs, incidents and use rates.

The Agency has removed the comparative risk assessment from the risk assessment. However, this analysis will be reviewed as part of the risk management phase of the process.

(13) Refined Risk Assessment

ETF Comments: These numbers should be changed after a refinement of exposure concentrations in consideration of realistic conditions as outlined by the ETF assessment submitted to EPA.

This statement ["… current endosulfan use rates on 88% of the crops modeled will exceed acute high risk LOCs more than 99% of the time."] is not justified. If the assumptions of such high risks would be true, many more incidents should be reported from actually registered uses of endosulfan.

While the toxicity data may indicate a high hazard, neither the incident data (after the time rate reductions and label changes including mitigation measures were in place) nor a truly refined risk assessment (c.f. assessment by Task Force, which was submitted in Oct. 1999, but not considered) indicate a high risk.

ETF appreciates the efforts of EPA to refine the Tier II exposure assessment and considering more realistic assumptions. However, one of the assumptions of considering the effect of the 300-foot buffer only for spray drift reduction is not realistic. In addition, in the PRZM/EXAMS modeling a number of sensitive parameters chosen by EPA are unrealistic and inappropriate:

- In the cotton scenario the curve numbers used were inappropriate. A curve number of 99 would yield higher runoff than from a farm road (PRZM manual Curve Number Table).
- PRBEN value of 0.5 for a compound like Endosulfan (having a high Koc) is inappropriate (0.9 should be used instead). If there is any relevant recent literature available as stated by the EPA addressing this issue, it should be quoted in the document.
- Aerobic Aquatic Metabolism Half-Life: EPA assumed aerobic aquatic half-life to 2 times the aerobic soil half-life (114 days for α-endosulfan and 416 days for β-endosulfan). This is not correct particularly for endosulfan, which is readily hydrolyzed in water. The aerobic aquatic studies submitted by the ETF (MRID: 44917801 and 44917802) was deemed as a supplementary study by the EPA. Therefore, the degradation rate (T½ for α- and β-endosulfan = 12 to 15 days and for total α-, β- and endosulfan-sulfate = 18 to 21 days) in the total sediment/water system from the above study should be used in the PRZM/EXAMS modeling. Using the correct values would produce significantly lower (acute and chronic) concentrations of endosulfan residues in the receiving water.

Due to these limitations with the exposure assessment conducted by EPA does not reflect realistic worst case scenarios and the results from the assessment are not appropriate to be used in further risk assessment. ETF submitted a refined exposure assessment including the influence of buffers on runoff and erosion losses (MRID# 44953103). ETF respectfully requests the EPA to use the results from this exposure assessment for their risk assessments.

Agency Response: This issue is one of differences in interpretation and not of scientific error. The Agency notes throughout its responses that its assessment used non-conservative inputs and does reflect "realistic" conditions that occur within the endosulfan use area. While the assessment does not attempt to model those sites which would not be prone to runoff, it does bracket its risk assessment between typical applications and maximum allowable label applications. The assessment is supported by the incident data, which show that several fish kill incidents attributable to endosulfan use are reported each year.

ETF Comment: The reference to the uncertainty should be deleted. The unusual high number of available study results for Endosulfan with a large number of species, especially in the aquatic environment provides a solid basis for the risk assessment.

Agency Response: While a number of studies have been submitted to the Agency 22% of those studies submitted were classified as acceptable and provided useful information for inclusion in the ecological risk assessment.

(14) Data Gaps

ETF Comment: Based on existing studies to be submitted to EPA it can be established that endosulfan sulfate is as toxic to fish and aquatic invertebrates as the parent compound(s). Therefore a risk assessment could be based on the toxicity of α-endosulfan and β-endosulfan without the performance of additional studies with the sulfate.

Agency Comment: The Agency accepts that the available scientific evidence points to endosulfan sulfate being as toxic to fish and aquatic invertebrates as the parent compound. The risk assessment will reflect that endosulfan sulfate is equal in toxicity to the parent compounds. The risk assessment was based only on the toxicity of the parent compounds and did not include the added toxicity that might be contributed by the presence of endosulfan sulfate in the water. Such consideration would have resulted in an assessment of greater risk than is noted in the current risk assessment.

ETF Comment: ETF is therefore respectfully requesting to modify the study requirements as follows: [Table provided on p. 5-6; 29].

Agency Response: The Agency will review the studies as they are submitted. However, the Agency does not expect the risk assessment conclusions to be impacted greatly by the results of these studies.

The data are intended to confirm reports that endosulfan sulfate degradate has toxicity similar to that of the parent. The data will not have an impact on the current assessment of risk since the toxicity of the degradate was not considered in calculating RQ values. It is possible that the additional data could increase Agency concerns regarding the cumulative toxicity of the parent endosulfan and its degradate.

(15) Miscellaneous Issues and Error Corrections

Executive Summary/ Environmental Risk Characterization

ETF Comments: The highest RQ values is "487", as stated on page 23, not "697". Also this value is based upon exposure assessments which the ETF contests do not even represent the realistic worst-case.

The value of 680 is wrong. Even if based on the draft RED, the highest value is 487, and this value (Table 15) is based on a study rendered "Invalid" by EPA. Similarly, the ETF contests the exposure estimates, which if considered would further reduce risk quotients.

Agency Response: The Agency concurs with the ETF's comment that the RQ value of 680 is incorrect and the assessment has been corrected to reflect the fact that the highest reported RQ value is 487. The estuarine/marine study, *i.e.*, striped bass, used in the calculation of this RQ was incorrectly identified as "invalid"; the study has been classified as supplemental.

Introduction

ETF Comment: The Endosulfan Task Force (ETF) is not supporting the above-mentioned ULV liquid spray, the insecticidal smoke tablets or similar impregnated materials containing endosulfan. The ETF members submitted requests in 1999 and amended the ETF technical labels to delete these and other non-food, non-agricultural uses. The official Notice for the use-deletions was published in Federal Register on July 19, 2000. The 30-day commenting period has since expired and the use deletions should become effective after January 2001.

Agency Response: These formulations have been deleted. Since the risk assessment did not consider these formulations, deleting them will have no impact on the assessment.

ETF Comment: The ETF does not support any of those listed combination products. [dimethoate, malathion, methomyl, monocrotophos, pirimibcarb, triazophos, fenoprop, parathion, petroleum oils, and oxine-copper.

Agency Response: One of the labels supported by the ETF (registration number 279-3222; product name Methyl Parathion 2 Thiodan 3EC) is a combined formulation of endosulfan with methyl parathion. The other listed combinations will be deleted.

Fate Assessment

ETF Comment: This ["endosulfan represents a mixture of two chemically distinct pesticides…"] is a misleading term and should be rephrased. This implies that technical grade endosulfan has two different compounds, where as in fact it contains one compound, exhibiting isomerism. The sentence could be rephrased as ". . . technical grade endosulfan represents a mixture of two biologically active isomers that differ in physico-chemical properties."

Agency Response: The assessment has been revised to note that technical grade endosulfan is a mixture of two biologically-active isomers with physico-chemical properties different enough to separate each as a distinct pesticide.

ETF Comment: The results of a number of studies submitted by the ETF should also be listed:

water solubility - MRID# 41421502

vapor pressure -MRID# 41421501
octanol/water coefficient - MRID# 41421503
photolysis in water - MRID# 41415700
aerobic aquatic metabolism – MRID# 44917802
batch equilibrium – MRID# 41412905
runoff studies - MRID# 41309701, 44903601
farm pond study - MRID# 41164101

Agency Response: Those referenced studies which have been reviewed and found to be acceptable will be added as appropriate. The photolysis in water and aerobic aquatic metabolism studies were reviewed and found to be unacceptable. One of the runoff studies was already included in the assessment. The second runoff study and the farm pond study provided supplemental, but limited, information and will be added. The Agency also notes that Table 1 summarizes the important fate studies and is not meant to be exhaustive. Several studies not mentioned in this table are included in the fate assessment.

ETF Comment: Delete "fish" in the column "Parameter," in as mussel are mentioned under "Value." The accumulation factor for edible tissue should be 2249 instead of 2429. It also should be added that there was no detection of residues after 48 h of depuration.

Agency Response: Table 1 has been revised to read "in Non-Target Aquatic Species." The Agency reviewed Accession Number 05005824 and found that the value reported in that study was 2429.

ETF Comment: The reference is missing (MRID# *...)*.

Agency Response: Because the particular section to which this comment refers is an overview/summary, the individual MRID references aren't necessary here. EFED provided the references in the more detailed discussion that follows this section.

ETF Comment: Additional important publications need to be considered for this chapter (Bidleman et al.,1990, Organic Contaminants in the Northwest Atlantic Atmosphere at Sable Island,1988-1989, Chemosphere; 1992, p.1389-1412; Hoff et al., 1992; Annual Cycle of Polychlorinated Biphenyls and Organohalogen Pesticides in Air in S. Ontario; Environm.Sci.Technology; 1992, 26,2; 166-175; Simonich & Hites, 1995; Global Distribution of Persistent Organochlorine Compounds; Science; 1995; 269; 1851-1854). Based on these publications Endosulfan is detectable only in very low concentrations in the air during the time of application and decreases to extremely low levels during off-season. The extremely low traces occasionally found in remote areas were not confirmed in each case.

Agency Response: The Agency will consider the additional studies during the public comment period. If any of the studies add to our understanding of endosulfan, they will be included in the final ecological risk assessment.

ETF Comment: Half-lives for total Isomers (α+ β) are different in the reports compared to what is presented in Table 2. Values should be changed accordingly.

Trial	EFED value	Report value
Donaldsville (bare ground)	172	76
Donaldsville (tomatoes)	155	75
Tulare county (bare ground)	89	97
Tulare county (cotton)	93	90
Poplar (bare ground)	nd	9-13
Poplar (cotton)	nd	10-15

Agency Response: The Agency does not rely solely on registrant-calculated values, but calculates the half-lives using all of the available data. For clarity, table 2 will be revised to include half-life values for the individual isomers, the combined isomers, and the total isomers plus endosulfan-sulfate residues.

ETF Comment: MRID# 44403102 should be added to the citations and used for modeling. The results from this study indicate foliar half-lives of 0.6 – 3 days.

Agency Response: The MRID citation needs to be reviewed to determine what it represents and its applicability for use in determining foliar dissipation half-life values (which will depend on how the study was conducted, under what conditions). Given that the reported half-life values are within the range of already-reported values, this study will likely have minimal impact on the input value used for foliar modeling.

ETF Comment: A reference should be added. The bioconcentration factor was 2200X, not 2400X. There should also be mention of the fact that the residues in fish are completely depurated after 48 h in clean water.

Agency Response: The Agency checked Accession Number 05005824 and found that the value reported was indeed 2429.

Water Assessment

ETF Comment: This chapter ["Drinking Water Exposure Assessment"] should be deleted. The drinking water assessment is already covered in the HED document and of little relevance for assessing the risk to the environment.

Agency Response: The drinking water assessment is conducted as part of the general assessment of impact of pesticide use on water resources. Thus, it is included in the ecological risk assessment. The risks associated with exposure through drinking water is contained in the human health assessment.

Ecological Risk Assessment

ETF Comments: The LD_{50} for bobwhite was reported in MRID# 137189 as 42 mg/kg (as stated on page 86). For ducks, the range of LD_{50} values (28 to 33 mg/kg) for the different studies (see p.86) should be reported [in summary Table 9] instead of just the lowest value.
In summary table [10] either means, medians, or ranges should be reported instead of the lowest value; e.g. the available results for the 96hr LC50 Trout using endosulfan technical, range from 0.8 to 1.5 ppb; reported was the lowest value (0.8 ppb). The referenced value for the bluegill sunfish (LC50=1.7 ppb, MRID# 38806) is from a test using pure endosulfan technical (100%).

The more appropriate LC50 from testing with 96% technical material should be based on two studies from Pickering & Henderson (MRID# 05014941) with values of 3.3 to 4.4 ppb. The listed value for the scud is a 96-h value, and not 48-h.

Agency Response: As noted earlier, EPA's policy is to initially conduct deterministic evaluations using peak exposure values and the most sensitive endpoints. Only in more refined assessments are exposure and effect estimates revised to less conservative values. Thus, where the ETF believes that ranges should be depicted or that less conservative values be used as toxicity endpoints, such deviations would not be consistent with the current approach used in the evaluation of other chemicals.

ETF Comment: A reference for the acute value in rats is missing [from Table 9].

Agency Response: The reference will be added.

ETF Comment: The reference of Mayer & Ellersieck (1986, MRID# 05008271) is not in any reference list.

Agency Response: As noted in the reference section, the Agency only included citations for those references which do not have assigned MRID or Accession numbers. Mayer and Ellersieck has an MRID number and, thus, would be covered in the overall listing of MRID references in support of the risk assessment.

Ecological Hazard Assessment

ETF Comment: Terrestrial and aquatic RQs should be changed. The Agency needs to consider the submitted risk assessment and product specific residue data (see above MRID# 40261301) for these evaluation. We believe that the deterministic approach of calculating single RQs using single EECs (maximum/average), LC50/LD50 (lowest value available), NOAEC (lowest value available) or using surrogate data (Kenaga monograph) instead of endosulfan specific data is not appropriate and does not reflect the real life picture. This evaluation needs modifications using more probabilistic assessments.

Agency Response: The RQ assessments are standard practice in Agency screening-level assessments. In this particular case, these assessments indicated a problem, so the Agency performed refined assessments in the case of aquatic exposure assessments. The same could have been done for the terrestrial exposure. In such refinements, the Agency will need to take into account the contributing toxicity of endosulfan sulfate, which was not included in the initial assessments.

Ecological Risk Characterization

ETF Comments: Typographical error [p. 27]: "result of intentional misuse" [p. 30] typographical error [p. 32] "stripped bass " instead of "striped bass". [p. 34] Typographical error [p. 35] "flathead minnow" instead of "fathead minnow". [p. 35]
Agency Response: These typos will be corrected.

Actual Use Characterizations for CA

ETF Comment: Some of the values [reported in Table 17 for typical and seasonal application rates in CA] reported are incorrect.

The highest seasonal application rates are e.g. for grapes up to more than 10 times (33 lb a.i./A) of the maximum allowable seasonal label rate. Also the lowest reported rates (lettuce 0.03 lb/acre) are below any effective (and recommended label) application rate.

Agency Response: The values are from a survey of actual use and have been provided by the users.

Appendix A (Fate Studies)

ETF Comments: It is not transparent how EPA calculated the half-lives [in Table A-2]. DT50 values calculated by the registrant differ from those listed in the table.
The cited half-lives need to reflect the above mentioned revisions.
Agency Response: The Agency calculated the half-lives using non-linear regression (ln-transformed data) with no data censoring.

Agency Comment: This statement [Extractions of the soil do not appear to be exhaustive, in review of aerobic aquatic metabolism study] should be deleted. Triplicate extractions in the extraction scheme seem to have not been noticed in the evaluation of the study.

EFED Response: The study in question was revised (MRID# 44917801) to confirm that the sediment samples were indeed extracted three times with a mixture of acetonitrile and toluene (4:1 by volume). This information is not transparent in the body of the study, but it was obtained from one of the figures. The statement, however, does not affect the Science Chapter, or the decision to reject the study, because the study presented several other deficiencies.

ETF Comment: A study [mobility of degradates] is missing (MRID# 41412905), the results of which are in agreement with the K_{OC} calculations presented on page 3, Table 1.

Agency Response: This is indeed the same study mentioned in Table 1. The study was originally reviewed and rejected by OPP for a number of reasons. However, while the study flaws prevent us from using the results quantitatively, it does provide a qualitative sense of the relative mobility of the degradates.

Appendix B (Fate & Transport Lit Rev)

ETF Comments: Alleged estrogenic effects, especially if not true, should not be part of fate and transport discussions. The presentation of toxicity values in the context of environmental fate discussions is misleading and should be deleted.

Agency Response: The appendix title will be revised to reflect that it contains selected published literature used to support the ecological assessment, and not solely the fate and transport assessment.
ETF Comment: The physico chemical properties presented by Montgomery (1993) and McConnell et al (1998) are a secondary source of information (i.e. not original papers), and as such should not be quoted.

Agency Response: While nothing precludes EPA from using such secondary sources of information, EPA acknowledges these need to be noted as such. In this instance, the Agency intended to delete that particular table; the deletion will be done in the revised chapter.

ETF Comment: All of the reported values for Endosulfan in surface waters (see Table B-7) are below the reported limit of detection (<5 ppt), which should be a definite value (not "less than"). The limit of quantification and detection for the total method (including SPE) are not reported.

Agency Response: This will be clarified.

Appendix C (Water Modeling)

ETF Comments: Spray Efficiency: Table C-1 states spray efficiency as 75 %. However, the model input files have spray efficiency as 99 %. ETF used 95 % as spray efficiency in its exposure assessment (MRID# 44953103).

Spray Drift: In Table C-1 spray drift is mentioned as 5 % of applied. However, the input files indicate 0 % due to the presence of the 300-ft buffer.

Agency Response: Spray drift efficiencies are based on results of the Spray Drift Task Force study. Table C-1 will be revised to note that in the initial assessment, 5% spray drift was used. However, in the revised assessment, no drift was simulated – a value that is not conservative, since some drift will reach the water body even with a 300-foot buffer.

Appendix E (Ecological Studies)

ETF Comment: Rainbow Trout (MRID# BA007902), the indicated % ai of 86 must be an error; usually the technical material is 96% a.i. [p. 40]
Macek et al (1976) report the LC_{50} of 0.86 mg/L for the fathead minnow (Pimephales promelas) and not for a flathead catfish (Pylodictis olivarius) as stated in the table. [p. 41]
Typographical error [text above Table E-8]: "formulation of" [p. 41]
Typographical error [text above table F-6]: "acute" [p. 43]
Typographical error: "granivore" [on p. 125] [p. 43]
In the presentation of the formulation data it should be made clear if the results refer to total product (formulated) or a.i. (technical) [p. 41]
A reference should be provided for the Eastern Oyster [Table E-16] [p. 42]
The author of reference 16 should be "Fischer" [p. 42]
The exponents for the acute risk are missing [in Table F-6]. [p. 43]
exponent "b" should be "c" in places [Table F-13c] [p. 44]

Agency Response: These will be corrected.

ETF Comment: The chronic daphnia reproduction study is being re-classified in the text of the review. In Table 11 it is still classified as "core". The DER is needed to properly assess the reclassification and the statement that the requirement is (now) not fulfilled. Inconsistencies between the text, the classification of the studies and the reference list should be checked. For instance, the reference for acute toxicity studies by "Hudson et al." is cited with a MRID number of 160000 as "core" in Table E-1 on page 86. However, this reference is not contained in Table E-17 "Studies, classified as acceptable, that were submitted to support the reregistration of Endosulfan", but in Table E-18 "Studies that were submitted to support the reregistration of Endosulfan but did not pass initial screen. Data discrepancies responsible for rejection are listed" with the MRID number 05003462 and the comment "insufficient data." In the reference list on page 110 the study is classified as "supplemental, upgradable."

EFED Response: Discrepancies will be clarified.